IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)))))))))))	**Civil No. 04-12457 PBS**

DePuy Mitek's Response to Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Concise Statement of Material Facts in Support of Their Motion for Summary Judgment of Infringement

Defendants Fact 1:

Plaintiff DePuy Mitek, a Massachusetts corporation, and a Johnson & Johnson company, makes and sells medical products. Ex. 17.

DePuy Mitek's Response to Defendants Fact 1:

Undisputed.

Defendants Fact 2:

Defendant Arthrex, a privately held Delaware corporation, develops and sells medical products in the field of arthroscopic surgery. FiberWire suture and its related products TigerWire and FiberStick ("collectively "FiberWire") are among those products and are the ones accused of infringement of U.S. Patent No. 5,314,446 ("the '446 patent"). Ex. 16.

DePuy Mitek's Response to Defendants Fact 2:

Undisputed.

<u>Defendants Fact 3:</u>

Defendant Pearsalls, a United Kingdom company, is a braid manufacturer which makes the braids that eventually become FiberWire suture.

<u>DePuy Mitek's Response to Defendants Fact 3:</u>

Disputed to the extent that Arthrex suggests that Pearsalls is just a "braid manufacturer." Otherwise undisputed.

<u>Defendants Fact 4:</u>

Ethicon, a Johnson & Johnson company, is related to DePuy Mitek and the original owner of the '446 patent. Ex. 18.

<u>DePuy Mitek's Response to Defendants Fact 4:</u>

Disputed to the extent that the "original owners" were the inventors, otherwise undisputed.

<u>Defendants Fact 5:</u>

In 2001, Arthrex introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5.

<u>DePuy Mitek's Response to Defendants Fact 5:</u>

Denied to the extent the term "new" is undefined, and it is not clear in what way Arthrex means "new." Based on the information available to it, Mitek admits that before 2001, Arthrex did not sell a suture called FiberWire, and Arthrex introduced FiberWire in 2001. Denied that Arthrex's citation supports the position.

Fact 6:

FiberWire was so new and revolutionary that it spawned a new category of suture called "high-strength" suture. Ex. 2 at 2; Ex. 4 at 146:7-14.

DePuy Mitek's Response to Defendants Fact 6:

Denied. The phrase "new and revolutionary" is vague and ambiguous. Arthrex's evidence does not support this factual assertion. Arthrex's evidence only indicates that Arthrex was the first company to sell a "high strength" suture. Arthrex's evidence does not establish any causation between the sale of any "new and revolutionary" FiberWire and the creation of a new category of suture.

Defendants Fact 7:

FiberWire suture was the first "high-strength" suture introduced into the market. Ex. 2 at 2; Ex. 4 at 146:7-14.

DePuy Mitek's Response to Defendants Fact 7:

Undisputed.

Defendants Fact 8:

FiberWire was more than twice as strong as the sutures conventionally used in orthopedic surgery, including Ethibond, the leading suture for the orthopedic market sold by Ethicon. Ex. 2 at 8.

DePuy Mitek's Response to Defendants Fact 8:

Denied as vague as to the type of "strength" is undefined. Denied based on lack of evidentiary support. Arthrex's evidence does not show that FiberWire is twice as "strong" as Ethibond. For example, size 3-0 FiberWire has a knot strength of 2.60 Kg and size 3-0 Ethibond has a knot strength of 2.06 Kg (Arthrex Ex. 2 at 8).

Defendants Fact 9:

FiberWire obtains its strength because it contains ultra high molecular weight polyethylene ("UHMWPE"), one of the strongest synthetic materials ever created. Ex. 3 at § 1.

DePuy Mitek's Response to Defendants Fact 9:

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. Mitek further objects to the admissibility of this exhibit under authenticity grounds under FED.R.EVID. 901. The term "strength" is vague and ambiguous. FiberWire does not obtain its "strength" from just UHMWPE. Don Grafton, Arthrex's developer of FiberWire, testified at his deposition that knot tie down, which he defined as related to knot strength (Mitek Ex. 1 at 26:14-27:6), would be poor with a 100% UHMWPE suture (*id.* at 26:14-31:1; 52-53). Furthermore, Arthrex's 234 patent states that "[o]ne of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema and Spectra. However, this material, while stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical application" (Mitek Ex. 2 at 1:13-21). Also, Dr. Brookstein has opined that FiberWire's various "strength" characteristics are not due to just UHMWPE (Mitek Ex. 3 at ¶¶19, 20, 38, 39). Further, Mr. Grafton testified that a braid of just UHMWPE could not hold a knot (Mitek Ex. 1 at 46:10-15). Denied that Arthrex has proven that the ultra high molecular weight polyethylene is one of the strongest synthetic materials ever created.

Defendants Fact 10:

After seeing the impact of FiberWire, DePuy Mitek realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5.

DePuy Mitek's Response to Defendants Fact 10:

Denied, as the factual support does not support the factual averment. The document refers to "business plan objective" and does not refer to sales targets as Arthrex fact suggests. Admitted that Mitek lost sales to Arthrex's FiberWire product.

Defendants Fact 11:

DePuy Mitek's original idea was to introduce a "me too" suture that mimicked FiberWire. Ex. 5. In late 2004, DePuy Mitek introduced its own high strength suture called Orthocord, which also includes UHMWPE. Ex. 6.

DePuy Mitek's Response to Defendants Fact 11:

The first sentence is denied. The terms "mimicked" and "original" are vague and ambiguous. This fact is denied to the extent it suggests that DePuy Mitek copied the design of Arthrex's FiberWire. Orthocord has a different design. Disputed with respect to "late 2004" being vague and ambiguous.

Defendants Fact 12:

Shortly before filing this lawsuit, the '446 patent was assigned from Ethicon to DePuy Mitek. Ex. 7. In this lawsuit, DePuy Mitek alleges that defendants infringe claims 1, 2, 8, 9 and 12 of the '446 patent ("the asserted claims").

DePuy Mitek's Response to Defendants Fact 12:

Undisputed.

Defendants Fact 13:

Neither Ethicon nor DePuy Mitek has never made a commercial product covered by the '446 patent. The '446 patent is a paper patent. Ex. 9.

DePuy Mitek's Response to Defendants Fact 13:

Mitek cannot answer with respect to the first sentence because it has three negatives "neither, nor, and never," and it is not clear what Arthrex intends by this statement. The term "paper patent" is not defined and there is no such "paper patent" doctrine recognized by law. To the extent Arthrex is suggesting that the invention has not been commercialized, Arthrex is wrong because FiberWire is an infringement (Mitek Ex. 3 at ¶¶16-64; Mitek's Memorandum in Support of Its Motion for Summary Judgment and exhibits cited therein)

Defendants Fact 14:

Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at 103:23-104:17.

DePuy Mitek's Response to Defendants Fact 14:

Undisputed.

Defendants Fact 15:

At the time, a standard braided suture was Ethibond, a suture made entirely of PET polyester, which was braided to form the suture. Ex. 4 at 135:4-7.

DePuy Mitek's Response to Defendants Fact 15:

Denied because the asserted fact is vague regarding "at the time" and the field of use is not specified. Arthrex's supporting evidence explains the construction of Ethibond but not anything with respect to being a standard during any particular time (Arthrex Ex. 4 at 135:4-7).

Defendants Fact 16:

Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

DePuy Mitek's Response to Defendants Fact 16:

Denied because Dr. Steckel's "idea" and "goal" was not so limited, and Arthrex's citations do not support such a limitation on Dr. Steckel's "idea" and "goal." Further, Dr. Steckel did not testify that he had only one idea and one goal. For example, in the 446 Patent, Dr. Steckel explains that his concept was broader and included many other concepts (Arthrex Ex. 8 at 2:40-62; 3:40-51; 4:9-14). Arthrex's fact takes Dr. Steckel's testimony out of context and mischaracterizes Dr. Steckel's testimony and omits the testimony on the following pages of his deposition where he testified that his ideas and goals were not so limited:

> Q. -- was it an object of the patent to try
> and produce a suture stronger than Ethibond?
> A. (Witness reviews document.) I would say
> since we're clearly looking at aromids, I would say
> the answer was yes.

Q. And that was by using an aromid?
A. No. That would be one way of doing it.
Q. Is there anything --
A. We were certainly looking at fiber. We were certainly considering fibers that offer higher tensile strength than -- than strictly PET.
Q. And that was the aromids?
A. That was one of -- that was one example.
Q. Is there anything else?
A. Well, the patent describes generic classes of polymers, and the high strength aspect of it has more to do with how those polymers were processed. So, any of those polymers that are listed, you know, could be processed in a high strength form or a medium-strength form or a low-strength form.
Q. When you're saying, "these," which ones are you talking about?
A. I'm referring to the polymers listed in the claims.
Q. All of them?
A. All of those can be processed to get a range of low, medium, or relatively high strength.

(Mitek Ex. 4 at 105:17-106:24) (objections omitted).

<u>Defendants Fact 17:</u>

Ethicon built and test heterogeneous braids, made of PTFE and PET, by February 2, 1989. None of these braids, however, were sterilized. Ex. 19 at 225:5-8.

<u>DePuy Mitek's Response to Defendants Fact 17:</u>

Mitek admits the first sentence of Arthrex's fact #17. Mitek denies the second sentence. Arthrex's cited evidence only states that Dr. Steckel "believe[d]" that the braids were not sterilized at that point in the process, not that the braids were not sterilized (Arthrex Ex. 19 at 225:5-8).

Defendants Fact 18:

Ethicon never built a sterilized surgical suture that included all the limitations of the asserted claims before the filing date of the '446 patent. Ex. 10 at 345:7-10.

DePuy Mitek's Response to Defendants Fact 18:

Denied. Arthrex cites to Dr. Hermes' testimony, but Dr. Hermes said that "I don't know" whether the braids built by Ethicon were sterilized (Arthrex Ex. 10 at 345:14). Arthrex's cited evidence does not support the factual assertion that "Ethicon never built a sterilized surgical suture that included all the limitations of the asserted claims before the filing date of the '446 patent." Also, denied based on Dr. Hermes testimony and Dr. Steckel's work (Mitek Ex. 5 at ¶¶31-43).

Defendants Fact 19:

During his development work, Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down even without a coating." Ex. 21 at DMI 2666.

DePuy Mitek's Response to Defendants Fact 19:

Undisputed that Dr. Steckel made this observation but denied to the extent that Arthrex suggests that Dr. Steckel ever intended to exclude coatings. Dr. Steckel testified and explained otherwise in the 446 Patent (Mitek Ex. 4 at 308:8-11; Arthrex Ex. 8 at 6:5-18).

Defendants Fact 20:

Dr. Steckel knew during the development work that led to the '446 patent that UHMWPE had great strength. Ex.5 (to *Markman* Brief) at 190:12-191:3.

DePuy Mitek's Response to Defendants Fact 20:

Denied because vague as to type of "strength" and "great." Mitek admits that Dr. Steckel testified as he did on pages 190:12-191:13 of his deposition (Arthrex Ex. 5 to *Markman* Brief).

Defendants Fact 21:

Ethicon filed the application that led to the '446 patent on February 19, 1992, three years after Dr. Steckel tested the braids. Ex. 8 at cover page.

DePuy Mitek's Response to Defendants Fact 21:

Denied because "the braids" are undefined and there is no antecedent basis. Undisputed that Ethicon filed the application that led to the '446 patent on February 19, 1992, three years after Dr. Steckel tested the braided sutures that are discussed in his February 1989 lab notebook entry.

Defendants Fact 22:

The specification of the '446 patent begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 8 at col. 1, ll. 5-25.

DePuy Mitek's Response to Defendants Fact 22

Denied. Mitek admits only that the 446 Patent (Arthrex Ex. 8) states what it states on column 8, lines 5-25, and that statement is not present in the cited evidence.

Defendants Fact 23:

The specification cautioned that mechanisms, such as coating, will adversely affect braid mobility and explained that "the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid." Ex. 8 at col. 1, ll. 26-29.

DePuy Mitek's Response to Defendants Fact 23:

Denied. The citation from the 446 Patent does not discuss "braid mobility" and that term is not defined here. Further, no effects of coating on "braid mobility" are discussed in the cited evidence. Further, this "fact" mischaracterizes the '446 patent and takes the quoted passage out of context (Arthrex Ex. 8 at 1:16-29). Denied to the extent that Arthrex tries to make a universal statement about all coatings that is not supported by the evidence and not true. The 446 patent recognizes that not all coatings will cause the fibers or yarns to adhere to one another (Arthrex Ex. 8 at 6:11-13).

Defendants Fact 24:

The first example presented in the specification is coating, which "improve[s] handling properties," but at the expense of braid pliability. Ex. 8 at col. 1, ll. 29-31.

DePuy Mitek's Response to Defendants Fact 24:

Denied. The cited evidence does not say anything about "the expense of braid pliability." Further, denied because the term "first example" is undefined. The first example discussed in the 446 Patent is a "braided multifilament" (Arthrex Ex. 8 at 1:6). This "fact" mischaracterizes the '446 patent and takes the quoted passage out of context. The 446 patent recognizes that not all coatings affect braid pliability (*id.* at 6:5-17).

Defendants Fact 25:

The specification suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." Ex. 8 at col. 2, ll. 22-28.

DePuy Mitek's Response to Defendants Fact 25:

Denied. Mitek admits that the cited passage states that:

> If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

(Arthrex Ex. 8 at 2:22-28). The passage says that "in most cases," not all cases, the braid will be relatively weak and unusable. Also, it refers to "highly lubricous polymers [that] are used in thetraditional manner" not just "highly lubricous polymers. Mitek denies that this paragraph has the meaning that Arthrex subscribes to it (Mitek Ex. 5 at ¶¶49-54).

Defendants Fact 26:

This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." Ex. 8 at col. 4, ll. 50-54.

DePuy Mitek's Response to Defendants Fact 26:

Denied. Mitek disputes that the 446 Patent has such a theme (Arthrex Ex. 8 at 2:40-62; 3:40-51; 4:10-14, expressing broader concepts and combinations of materials). The 446 Patent never says that "lubricious polymers are too weak for suture usage" and in fact teaches embodiments that use lubricous polymers (*id.* at 4:9-32). Also, Arthrex's citation is to a "most preferred embodiment," not all embodiments (*id.* at 4:41-59).

Defendants Fact 27:

The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits "improved pliability and handling properties . . . without appreciably sacrificing" [the suture's] physical properties," (Ex. 8 at col. 2, lines 31-37), namely its "physical strength and knot security." Ex. 8 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 8 at col. 2, ll. 62-66; col. 6, ll. 7-8.

DePuy Mitek's Response to Defendants Fact 27:

Denied as vague. The fact does not say what the "proposed solution" that it references is for. Denied to the extent that Arthrex suggests that the 446 Patent has only "one solution" and not many embodiments of a range of properties from dissimilar yarns (Arthrex Ex. 8 at 2:40-66; 3:40-51; 4:11-13; 4:35-36), and Arthrex cites to preferred and most preferred embodiments. Denied as Arthrex picks and selects citations from the 446 Patent and ignores the totality of its teachings. Denied to the extent Arthrex suggests that the 446 patent is limited to this preferred embodiment (*id.* at 2:40-66; 3:40-51). Denied with respect to "repeated" as Arthrex cites to the same citation and alleges that the same citation is a repeat (*id.* at 2:66) and its other alleged repeated citation does not support Arthrex's statement (*id.* at 6:7-8). Denied with respect to Arthrex's characterization of the 446 patented invention (Mitek Ex. 3 at ¶¶25, 35; Mitek Ex. 5 at ¶¶49-54).

Defendants Fact 28:

The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 8 at col. 1, ll. 11-15, 24) and "bending rigidity," (Ex. 8 at col. 6, ll. 44-45, col. 8 at Table, ll. 44-46), which are the inverse of pliability.

DePuy Mitek's Response to Defendants Fact 28:

Undisputed.

Defendants Fact 29:

A handling property specifically identified in the '446 patent is "knot tie down." Ex. 8 at col. 6, ll. 7-8.

DePuy Mitek's Response to Defendants Fact 29:

Denied to the extent Arthrex has not defined what it means by "knot tie down" in this fact, and the term has been used differently (Mitek Ex. 1 at 26:14-27:6; Arthrex's Ex. 29). Mitek admits that column 8, lines 7-8 of the 446 Patent refers to "handleability and knot tiedown performance of the braid" but denies that it states that knot tie down is a handling property.

Defendants Fact 30:

The '446 patent relies on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength. Ex. 8 at col. 8, ll. 22, 35 and 38.

DePuy Mitek's Response to Defendants Fact 30:

This fact is vague because "this combination" is vague and ambiguous. Mitek admits that examples of a "most preferred embodiment" of PTFE and PET are discussed with reference to the rule of mixtures and some properties, but not all properties, of this most preferred embodiment are discussed with reference to the rule of mixtures (Arthrex Ex. 8 at 4:41-44; 6:59-8:35). Denied as the 446 does not make a point about "weak" materials and does specify any material as being a "weak" material. Further, the cited references do not state "highly pliable materials." The PTFE and PET materials are described differently (*id.* at 4:9-40). Denied to the extent Arthrex suggests that the 446 patent is limited to a preferred embodiment.

Defendants Fact 31:

The specification also discusses the use of coating on sutures. It explains that coating, if desired, can be added "to further improve the handleability and knot tiedown performance of the braid." The specification also states that it is better if coating is not used, explaining that if the braid "possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening." Ex. 8 at col. 6, ll. 5-17.

DePuy Mitek's Response to Defendants Fact 31:

Undisputed that the 446 Patent "specification discusses the use of coating on sutures," but denied with reference to the term "also" because it has no antecedent basis in the fact. Undisputed that the 446 Patent states that: "If desired, the surface of the heterogeneous braid can be coated to further improve knot tiedown performance of the braid" (Arthrex Ex. 8 at 6:5-8). Mitek disputes the remaining averments of Fact 31. The specification does not state it is "better" if coatings are not used. The 446 patent states that coatings can be used or not used (*id.* at 6:5-17).

Defendants Fact 32:

Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 8 at col. 4, ll. 11-27.

DePuy Mitek's Response to Defendants Fact 32:

Undisputed that the 446 Patent identifies the seven polymers PTFE, FEP, PFA, PVDF, PETFE, PP, and PE. Undisputed that in preferred embodiments, these seven yarns are identified as "lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid" (Arthrex Ex. 8 at 4:11-14). Denied to the extent that Arthrex implies that that the seven polymers are stated as only being for lubricity to improve the overall pliability of the braid" and ignores the "preferred embodiment" language, the "or compliance, and surface lubricity" language, and the broader teachings of the 446 Patent (*id.* at 2:40-63; 3:40-51).

<u>Defendants Fact 33:</u>

Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 8 at col. 4, ll. 35-40. The term PE is never associated with the "strength" yarns.

<u>DePuy Mitek's Response to Defendants Fact 33:</u>

Undisputed that the 446 Patent states that "in a more preferred embodiment, the lubricating yarns of the firs set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid." Denied to the extent that Arthrex is saying that PET, nylon, and aramid are the only "ones" that could be used for improving strength (Mitek Ex. 4 at 105:17-106:24; Mitek Ex. 3 at ¶¶18,19,36, 37). Denied to the extent Arthrex ignores the "more preferred embodiment" language and alleges that PET, nylon, and aramid are only identified as providing strength (Arthrex Ex. 8 at 4:33). Also, denied as there are no "strength yarns" defined in the 446 Patent, and Arthrex has not defined the antecedent for "the strength yarns." Denied as one of ordinary skill in the art reading the 446 Patent would understand that UHMWPE is disclosed and would be understood to provide certain strength attributes (Mitek Ex. 5 at ¶¶44-59), and strong yarns of PP and PVDF are also disclosed (Mitek Ex. 3 at ¶¶36-38). Further, Arthrex's expert, Dr. Mukherjee, admits that all *polypropylene* fibers are disclosed (Mitek Ex. 6 at 297:9-15), and ultra high molecular weight polypropylene has ultra high molecular weight forms (Ex 11 to Mitek Ex. 3 at 1:11-15; 2:7-14).

<u>Defendants Fact 34:</u>

Claim 1 of the '446 patent is to a surgical suture "consisting essentially of" a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Ex. 8 at claim 1.

<u>DePuy Mitek's Response to Defendants Fact 34:</u>

Undisputed.

<u>Defendants Fact 35:</u>

The remainder of the asserted claims ultimately depend from claim 1. Ex. 8 at claims 2, 8, 9, 12.

<u>DePuy Mitek's Response to Defendants Fact 35:</u>

Undisputed.

Defendants Fact 36:

Claim 1 defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid. Ex. 8 at claim 1.

DePuy Mitek's Response to Defendants Fact 36:

Denied. PTFE, FEP, PFA, PVDF, PETFE, PP and PE are not identified in the 446 Patent as being "pliable." Rather, they are identified in preferred embodiments as lubricating yarns, not pliable yarns (Arthrex Ex. 8 at 4:11-12). Also, these are preferred embodiments and not limiting properties (*id.*). Denied to the extent that Arthrex is saying that PET, nylon, and aramid are the only "ones" that could be used for improving strength. Denied to the extent Arthrex ignores the "more preferred embodiment" (*id.* at 4:33) language and alleges that PET, nylon, and aramid are only identified as providing strength (Mitek Ex. 3 at ¶¶18, 19, 36-38; Mitek Ex. 5 at ¶¶44-59). Denied as the 446 Patent provides a broader description of properties and one of ordinary skill in the art would understand that to be so (Arthrex Ex. 8 at ¶¶2:40-63; 3:40-51; Mitek Ex. 3 at ¶¶25, 35).

Defendants Fact 37:

As the application for the '446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from heterogeneous braids. Ex. 22.

DePuy Mitek's Response to Defendants Fact 37:

Undisputed that the '446 Patent as originally filed had two sets of claims one of which was for heterogeneous braids. Denied that the other set was for "surgical sutures made from heterogeneous braid." The 446 Patent original "surgical suture" claims do not recite that they were "made from heterogeneous braids" (Arthrex Ex. 22 at DMI00033-35).

<u>Defendants Fact 38:</u>

Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ethicon elected to pursue the surgical suture claims. Ex. 23.

<u>DePuy Mitek's Response to Defendants Fact 38:</u>

Undisputed that Ethicon was required to elect which set of claims it wanted to prosecute. Undisputed that Ethicon elected to pursue the surgical suture claims. Undisputed that the patent examiner observed that the heterogeneous braid and surgical suture claims were patentably distinct. Undisputed that the heterogeneous braid was deemed to be useful as a fishing line and the inventions were deemed patentably distinct since there is nothing in the record to show them to be obvious variants (Arthrex Ex. 23). Denied to the extent Arthrex states otherwise and contrary to the statements by the Examiner (Arthrex Ex. 23).

<u>Defendants Fact 39:</u>

As originally filed, the first suture claim required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the "consisting essentially of" limitation. Ex. 22.

<u>DePuy Mitek's Response to Defendants Fact 39:</u>

Denied. The phrase "first suture claim" is vague and ambiguous. The "first suture claim" requires more than that "the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact" (Arthrex Ex. 22 at DMI000035 at claim 21, depending on claim 1). For example, the claim recites that "each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material" (*id.*). Denied as "specific materials" is undefined in Arthrex's fact, and the claim recited "filaments of a fiber-forming material" are more specific than the yarns recited.

<u>Defendants Fact 40:</u>

In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess ("the Burgess application") (Ex. 8 to *Markman* Brief).

<u>DePuy Mitek's Response to Defendants Fact 40:</u>

Undisputed.

Defendants Fact 41:

The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ex. 8 (to *Markman* Brief). The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 23 at 4.

DePuy Mitek's Response to Defendants Fact 41:

Denied. The Burgess application does not disclose "a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester" (Mitek Ex. 5 at ¶59). Rather, Burgess discloses a "braided construction" but does not specify what the construction is or how the materials are used in that construction (*id.*). For example, Burgess does not disclose whether the "braided construction" is all one type of materials in the sheath and the other material in the core, which are not in direct intertwining contact or another construction (*id.*). Arthrex's expert Dr. Mukherjee admits that a core/sheath arrangement with all one material in the sheath and all another material in the core is a "braided construction" (Mitek Ex. 6 at 217:12-14; 218:23-219:3). Further, Arthrex's Exhibit 23 does not say that the Burgess application discloses "a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester." Arthrex's Exhibit 23 refers to a "braided construction" of "filaments" not yarns.

Defendants Fact 42:

In distinguishing the '446 patent from the Burgess application, Ethicon responded that because of its braided construction, "the fishing line of Burgess would have <u>poor</u> knot strength properties." [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE "gives the line <u>minimal</u> stretchability." [Emphasis in original.] Ex. 24 at 2.

DePuy Mitek's Response to Defendants Fact 42:

Undisputed that Burgess was distinguished as nonanalogous art. Denied to the extent that Arthrex takes isolated statements, characterizes them as the "response," and ignores other statements such as that fishing line and sutures have dissimilar property requirements and "there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines" (Arthrex Ex. 24 at DMI000196). Denied as the response does not refer to the "Burgess braid combination" and attributes nothing to a "braid combination" (Arthrex Ex. 24 at DMI000195). Denied that Arthrex implies that the response refers to UHMWPE yarns, when it refers to "braid filaments" and "thread" of ultra high molecular weight PE.

Defendants Fact 43:

Ethicon further explained that "although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties." [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. Ethicon also told the Patent Office that "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Ex. 24 at 3-4.

DePuy Mitek's Response to Defendants Fact 43:

Undisputed that in an office action response, Ethicon stated that "[a]lthough this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties" (Arthrex Ex. 24 at 3-4). Ethicon did not "conclude[d] that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art" (*id.* at 4). Ethicon stated that "[i]n view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines" (*id.*). Ethicon did not say "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Rather, Ethicon said that "[e]ven if [a medical designer] did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture" (*id.* at 4-5).

Defendants Fact 44:

Later during prosecution, Ethicon made two amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 25 at 1. The allowed claims were limited to so that the dissimilar materials had to be from the group of specifically-named materials. Ex. 25.

DePuy Mitek's Response to Defendants Fact 44:

Denied. The originally filed claims required more than "only that that [sic] braid be made of two dissimilar materials (Arthrex Ex. 22 at DMI000033-35). Denied that Mitek "made two amendments to the claims" and "abandoned the broad claims." That fact is not supported by the citation. Also, the phrase "were limited to so that the dissimiliar materials had to be from the group of specifically-named materials" is vague, ambiguous, and unintelligible and not defined as to what group of materials it refers. Denied to the extent that Arthrex implies that the claim is limited in scope in some fashion to some specifically recited materials and no equivalents are available.

Defendants Fact 45:

The first set of yarns are from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 25.

DePuy Mitek's Response to Defendants Fact 45:

Denied to the extent Arthrex ignores that the yarns are composed of a plurality of filaments of a first fiber-forming material selected from a group consisting of certain select materials (Arthrex Ex. 25 at DMI0000258).

Defendants Fact 46:

The preamble of the claims was also amended to change the term "comprising" to "consisting essentially of." Ex. 25 at 1.

DePuy Mitek's Response to Defendants Fact 46:

Undisputed.

Defendants Fact 47:

UHMWPE is a stiff material. It is not a pliable material. Ex. 11 at ¶ 56; Ex. 10 at 306:20-307:4.

DePuy Mitek's Response to Defendants Fact 47:

Denied as the cited evidence does not support the factual assertion. Arthrex Ex. 11 at ¶56 does not say that UHMWPE is a "stiff material" and "is not a pliable material." Paragraph 56 refers to a *braid* of UHMWPE that Arthrex had requested be less stiff, not that the *material* is stiff. Also, Ex. 10 does not have pages 306 and 307.

Defendants Fact 48:

General purpose PE has been used in sutures and other materials for decades and is established as a general purpose commodity polymer. Ex. 3 at § 1.

DePuy Mitek's Response to Defendants Fact 48:

Denied. The term "general purpose PE" and "general purpose commodity polymer" are not defined and therefore vague and ambiguous. DePuy Mitek does not dispute that PE, including UHMW PE, has been used in sutures for decades. Mitek does not dispute that PE including UHMW PE has "general purposes" (Mitek Ex. 3 at ¶40), and PE including UHMW PE are "commodity polymers."

Defendants Fact 49:

UHMWPE was introduced as in fiber form in 1985 and is considered a specialized high performance product. Ex. 3 at § 1.

DePuy Mitek's Response to Defendants Fact 49:

Denied. Mitek does not dispute that UHMWPE was available in fiber form in 1985. Mitek does not dispute that it was known to use UHMWPE in sutures in the 1980's (Ex. 7 at DMI000159). Ultra high molecular weight polyethylene fibers were known prior to 1985 (*id.*). Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. Mitek further objects to the admissibility of this exhibit under authenticity grounds under Fed.R.Evid. 901. Mitek objects to its admissibility here. Thus, Mitek disputes that Arthrex has evidence to establish its facts. Nevertheless, denied as "specialized high performance product" is not defined. Nevertheless, Mitek disputes that §1 of this exhibit states that UHMWPE "is considered a specialized high performance product."

Defendants Fact 50:

General purpose polyethylene and UHMWPE are not substitutes for each other. Ex. 12 (to *Markman* Brief) at 22.

DePuy Mitek's Response to Defendants Fact 50:

Denied. The term "general purpose PE" is not defined and therefore vague and ambiguous. The term "substitutes" is vague and ambiguous and, as used, overbroad. UHMWPE is equivalent to PE as used in the 446 patent (Mitek Ex. 3 at ¶¶16-42). Arthrex's supporting citation is a conclusory statement with no support. Arthrex's lack proof that "general purpose polyethylene" and ultra high molecular weight PE are never substitutes for each other. In fact, the 446 Patent refers to "PE" generically (Mitek Ex. 5 at ¶¶44-58; Mitek Ex. 3 at ¶40).

Defendants Fact 51:

The key structural characteristics of UHMWPE and general purpose polyethylene, molecular weight and molecular structure very different. Ex. 3 at § 2.

DePuy Mitek's Response to Defendants Fact 51:

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. Mitek further objects to the admissibility of this exhibit under authenticity grounds under Fed.R.Evid. 901. The term "general purpose PE" is not defined and therefore vague and ambiguous. Both UHMWPE and PE are both polymers made from ethylene (Mitek Ex. 5 at ¶44). Denied as the context of "key structural characteristics are not defined," and the key structural characteristics are that they are both polymers made from ethylene. Denied with respect to "very different" as their molecular structure is not "very different" particularly in comparison to other structures (Mitek Ex. 5 at ¶44). Denied that PE having a molecular weight of "several hundred thousand" (which presumptively includes 999,999 and which Arthrex apparently contends is "general purpose PE") is "very different" from PE having a molecular weight of 1,000,000 (which Arthrex apparently contends is ultra high molecular weight PE.

Defendants Fact 52:

UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. Ex. 3 at § 2.

DePuy Mitek's Response to Defendants Fact 52:

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. The term "general purpose PE" is not defined and therefore vague and ambiguous. Arthrex has no admissible evidence to support this fact. Also, Denied to the extent that Arthrex is relying on an advertising brochure as a technical reference.

Defendants Fact 53:

UHMWPE exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose polyethylene. Ex. 3 at § 2.

DePuy Mitek's Response to Defendants Fact 53:

Denied. Ex. 3 is hearsay under FED.R.EVID. 802 and inadmissible. The term "general purpose PE" is not defined and therefore vague and ambiguous. Arthrex has no admissible evidence to support this fact. The phrase "much higher" is vague and ambiguous.

Defendants Fact 54:

DePuy Mitek's expert, Dr. Hermes' first impression when reading the '446 patent was that it "seem[ed] to teach away from UHMWPE." Ex. 14 (to *Markman* Brief); Ex. 10 at 336:23-23.

DePuy Mitek's Response to Defendants Fact 54:

Denied. Arthrex mischaracterizes the quoted passage and takes the testimony out of context. Dr. Hermes testified that his note in which the quoted phrase appears was directed to Dr. Mukherjee's statements in his report that a preferred embodiment of the invention seemed to teach away (Mitek Ex. 8 at 335:19-337:4). Dr. Hermes was not testifying to the overall scope of the 446 patent or that he thought it taught away (*id.*). Further, as Dr. Hermes testified, that was not his "first impression when reading the '446 Patent" (*id.* at 334:4-8; 334:25-335:6). Rather, it was his notes of what Dr. Mukherjee had said in reading Dr. Mukherjee's expert report and it was the *first time he had read Dr. Mukehrjee's report*, not the patent (*id.* at 334:4-8; 334:25-335:6).

Defendants Fact 55:

Based on the teachings of the '446 patent, Ethicon's statements in the prosecution history and the differences between general purpose polyethylene and UHMWPE, the term "PE" in the asserted claims of the '446 patent means general purpose polyethylene and does not include UHMWPE. Accordingly, FiberWire does not contain a material from the first set of yarns and does not infringe the asserted claims of the '446 patent literally or by the doctrine of equivalents.

DePuy Mitek's Response to Defendants Fact 55:

Denied. Arthrex's "factual" averments is not a fact, but a legal contention. Also, it has not support. The term "PE" as used in the 446 patent includes UHMWPE (Mitek Ex. 5 at ¶¶44-48; Mitek's Markman and Summary Judgment Briefs and Exhibits).

Defendants Fact 56:

The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. Ex. 8 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8; Ex. 8 at 110:14-20; Ex. 8 at 103:23—104:17.

DePuy Mitek's Response to Defendants Fact 56:

Denied. This is not a factual averment, but a legal contention. Denied based on Mitek's claim construction briefing and summary judgment briefing and exhibits cited therein. (*see generally* prosecution history distinguishing over certain bioabsorbable yarns and Arthrex Ex. 8 at 2:40-62). Denied that the concept is repeated throughout the specification and that Arthrex's citations support that. Denied as Arthrex has not cited to any of Dr. Steckel's here, and Dr. Steckel did not so limit his work (Mitek Ex. 4 at 102:21-103:9; 105:17-106:24).

Defendants Fact 57:

Multiple patents, including patents owned by Ethicon and its expert, and publications (including from Ethicon) indicate that coating affects handleability characteristics of a suture, including knot tie-down. This was also asserted by Ethicon and DePuy Mitek when they developed suture products and was confirmed by several Ethicon and DePuy Mitek witnesses. Ex. 34, col. 1, ll. 14-18; Ex. 35, col. 1, ll. 11-15; Ex. 36, col. 1, ll. 12-15; Ex. 37, col. 1. ll. 19-25; Ex. 29 at 11; Ex. 28 at 525; Ex. 39; Ex. 40; Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23; Ex. 14; Ex. 8 at col. 1, ll. 29-31; col. 6, ll. 5-8. As stated above, the '446 patent also states that coating improves the handling characteristics of the suture, including knot tie-down.

DePuy Mitek's Response to Defendants Fact 57:

Denied to the extent that this fact supports the proposition that the specific coating on FiberWire materially affects the basic and novel characteristics of the 446 patent (Mitek Ex. 3 at ¶¶43-62). Denied that any of the citations say anything about the materiality of the effects of FiberWire's coating or other coatings to the claimed invention. Denied to the extent that Arthrex refers to all coatings applied in any matter, and Arthrex is not specific as to any particular coating. Denied as Arthrex's expert, Dr. Burks, the only surgeon to testify on the issue, said he was not sure that he could tell the difference using gloves between coated and uncoated sutures in handleability and knot tie down, and said he could not always tell the difference, and characterized the differences due to coating as "subtle" (Mitek Ex. 9 at 71:21-72:23; 73:9-14; 87:7-13; 88:1-3; 9-10; 96:18-19; 96:24-98:3; 98:15-21). Denied with respect to "patents owned by" Mitek's expert, as it is not clear that either expert owns any patents that are relevant to this

action and it has not been proven here. Denied as the citation to Arthrex Ex. 36 does not refer to knot tie down. Denied as the citation to Arthrex Ex. 37 refers to knot tie down but not other characteristics. Denied as there is no page 525 to Arthrex's Ex. 28. Denied as Arthrex's Ex. 18 does not have a 295:23-296:7.

Defendants Fact 58:

FiberWire contains a coating to improve handling characteristics, including suture slide, knot tying and ease of passing suture through tissue. Ex. 14.

DePuy Mitek's Response to Defendants Fact 58:

Denied as Arthrex's expert, Dr. Burks, the only surgeon to testify on the issue, said he was not sure that he could tell the difference using gloves between coated and uncoated sutures in handleability and knot tie down, and said he could not always tell the difference, and characterized the differences due to coating as "subtle" (Mitek Ex. 9 at 71:21-72:23; 73:9-14; 87:7-13; 88:1-3; 9-10; 96:18-19; 96:24-98:3; 98:15-21).

Defendants Fact 59:

For the reasons stated above, coating affect the basic and novel characteristics of the asserted claims of the '446 patent and its inclusion in FiberWire precludes infringement of those claims.

DePuy Mitek's Response to Defendants Fact 59:

Denied. This is not a fact but an incorrect legal contention (See Mitek's Markman and Summary Judgment briefing and exhibits therein). Arthrex's fact incorrectly states the law. The proper question is whether the coating *materially* affects the basic and novel characteristics of the 446 patent. Denied as Arthrex's expert, Dr. Burks, the only surgeon to testify on the issue, said he was not sure that he could tell the difference with just using gloves between coated and uncoated sutures in handleability and knit tie down, and said he could not always tell the difference, and characterized the differences due to coating as "subtle" (Mitek Ex. 9 at 71:21-72:23; 73:9-14; 87:7-13; 88:1-3; 9-10; 96:18-19; 96:24-98:3; 98:15-21). Even assuming that the basic and novel characteristics are defined as Arthrex has defined them (which they are not) the coating does not materially affect the basic and novel characteristics (Mitek Ex. 3 at ¶¶43-62).

Defendants Fact 60:

United States Patent No. 5,318,575 ("the '575 patent") is prior art to the '446 patent. Ex. 15 at cover page; Ex. 8 at cover page.

DePuy Mitek's Response to Defendants Fact 60:

Denied. This is not a fact, but a legal contention. Nevertheless, denied as United States Patent No. 5,318,575 ("the '575 patent") is not prior art to the '446 patent (Mitek Ex. 5 at ¶¶31-

43). The 446 inventors actually reduced the claimed invention to practice as early as 1989 (*id.*). Also, the 446 inventors conceived the invention as early as June 1998 (Ex. 7 to Mitek Ex. 5 at DMI002617-19; Mitek Ex. 5 at ¶33), constructively reduced the invention to practice in February 1992 upon filing the application for the 446 Patent (Arthrex Ex. 8), and were diligent in reducing it to practice from before the filing date of the application for the 575 Patent (Mitek Ex. 4 at 284:4-287; Mitek Ex. 10; Mitek Ex. 11).

Defendants Fact 61:

Ethicon did not reduce to practice any product that included all the limitations of the asserted claims of the ‘446 patent before the filing date of the ‘446 because it never built a braid that was sterilized before the filing date, as shown above. “Sterilized” is a limitation of each asserted claim of the ‘446 patent. Ex. 8 at claim 1, 2, 8 , 9, 12.

DePuy Mitek’s Response to Defendants Fact 61:

Denied. Arthrex’s cited evidence only states that Dr. Steckel “believe[d]” that the braids were not sterilized at that point in the process, not that the braids were not sterilized (Arthrex Ex. 19 at 225:5-8), not that the braids were not sterile. Ethicon reduced to practice the claimed invention prior to the filing date of the 446 patent (Mitek Ex. 5 at ¶¶31-43). Ethicon constructively reduced the invention to practice upon filing the application for the 446 Patent (Arthrex Ex. 8).

Defendants Fact 62:

The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent. The ‘575 patent discloses a surgical suture. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59; Ex. 10 at 212:25-213:5.

DePuy Mitek’s Response to Defendants Fact 62:

Denied. Arthrex and Dr. Mukherjee have both admitted that the 575 Patent does not disclose every limitation of the asserted claims in prosecuting its 234 Patent (Ex. 3 to Mitek Ex. 5 at DMI041091; Mitek Ex. 6 at 182:23-183:17). The ‘575 patent does not disclose every limitation of the asserted claims of the ‘446 patent, and does not disclose a suture having all of the claim limitations (Mitek Ex. 5 at ¶9-30). Denied as the cite to column 2, line 62, and column 3, line 2 is to a sternum closure device (Mitek Ex. 5 at ¶16). Denied as the cite to column 3, lines 8 and 15 do not specify any construction. Denied as the cite to column 7, lines 26 and 38 is to a 100% Spectra product, and the cites to lines 43 and 59 are to a polyester braid with a spectra core (*id.* at ¶20). Denied as the citations to Ex. 10 do not say anything about the disclosure of Chesterfield. Also, Dr. Hermes has identified braided constructions that are not in direct intertwining contact (*id.* at ¶¶30, 59). Dr. Mukherjee agrees that there are braided constructions that are not in direct intertwining contact (Mitek Ex. 6 at 217:12-14; 218:23-219:3).

Defendants Fact 63:

The '575 patent discloses a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Ex. 15 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12; Ex. 15 at claim 1.

DePuy Mitek's Response to Defendants Fact 63:

Denied. Exhibit 15 at 2:65-3:2 does not disclose anything about different yarns. It refers to filaments. Claim 1 does not specify direct intertwining contact (Mitek Ex. 5 at ¶21). Dr. Mukherjee admits that braided construction includes all of one material in the sheath and all of one material in the core (Mitek Ex. 6 at 217:12-14; 218:23-219:3). Dr. Hermes has specified braided constructions which are not direct intertwining contact (Mitek Ex. 5 at ¶¶30, 59).

Defendants Fact 64:

FIG. 6 of the '575 patent discloses a spiroid braid with several yarns (items 26) that are braided in "direct intertwining contact." Ex. 10 at 201:24-202:5.

DePuy Mitek's Response to Defendants Fact 64:

Denied. The citation does not says that "several" yarns are braided in direct intertwining contact (Arthrex Ex. 10 at 201:24-202:5).

Defendants Fact 65:

The '575 patent discloses that one of the yarns braided together to form a suture is UHMWPE. Ex. 15 at col. 2, l. 31; Ex. 10 at 197:12-25

DePuy Mitek's Response to Defendants Fact 65:

Denied. Column 2, line 31 refers to a tape. The citation to Arthrex Ex. 10 refers to a "fiber," not a yarn, and does not refer to a "suture." Denied to the extent Arthrex has not identified what "braided together" means, and Arthrex has admitted that there is no braided structure that anticipates (Ex. 3 to Mitek Ex. 5 at DMI041091; Ex. 6 at 182:23-183:17; *see also* Mitek Ex. 5 at ¶¶9-30).

Defendants Fact 66:

The ‘575 patent discloses that one of the yarns braided together to form a suture is PET or nylon. Ex. 15 at claim 11; claim 12; Ex. 10 at 198:7-11, 14-18.

DePuy Mitek’s Response to Defendants Fact 66:

Denied. Arthrex and Dr. Mukherjee have both admitted that the 575 Patent does not disclose PET or nylon disclosed with UHMWPE (Ex. 3 to Mitek Ex. 5 at DMI041091; Ex. 6 at 182:23-183:17). Denied as the 575 Patent does not disclose PET or nylon braided together with another material in direct intertwining contact (*id.*; Mitek Ex. 5 at ¶¶9-30). Also, Dr. Hermes has identified braided constructions that are not in direct intertwining contact (Mitek Ex. 5 at ¶¶30, 59). Denied as claims 11 and 12 of the 575 Patent do not disclose “braided together,” braided in direct intertwining contact, as opposed to core sheath, by Arthrex’s own admission (Ex. 3 to Mitek Ex. 5 at DMI041091; Ex. 6 at 182:23-183:17; *see also* Mitek Ex. 5 at ¶¶21).

Defendants Fact 67:

The ‘575 patent discloses that the suture is attached to a needle. Ex. 15 at col. 5, ll. 41-42.

DePuy Mitek’s Response to Defendants Fact 67:

Denied as the fact has no antecedent for “the suture.”

Defendants Fact 68:

The ‘575 patent discloses that UHMWPE can be constitute a volume fraction in the braided sheath and core from about 20-80%. Ex. 15 at col. 4, ll. 8-24; Fig.6.

DePuy Mitek’s Response to Defendants Fact 68:

Denied as unintelligible with respect to “can be constitute.” The ‘575 patent does not disclose that UHMWPE can constitute a volume fraction in the braided sheath and core from about 20-80% (Mitek Ex. 5 at ¶¶28-29).

Defendants Fact 69:

For these reasons, the ‘575 patent renders the asserted claims of the ‘446 patent invalid for anticipation.

DePuy Mitek’s Response to Defendants Fact 69:

Denied. This “fact” improperly calls for a legal conclusion. The ‘575 patent does not render the asserted claims of the ‘446 patent invalid for anticipation (Mitek Ex. 5 at ¶¶9-43). The 575 patent is not prior art (*see* Mitek’s Response to Fact #60).

Mitek's Facts Submitted In Response To Arthrex's Summary Judgment Motion

Mitek Fact 128

The 446 Patent claims all recite a surgical suture that consists essentially of a braid composed of a first and second set of continuous and discrete yarns, where

> each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and ***PE***.

(Arthrex Ex. 8 at 8:63-10:19).

Mitek Fact 129

Mitek's expert, Dr. Brookstein, also notes by declaration that ultra high molecular weight PE has many uses (Mitek Ex. 3 at ¶40).

Mitek Fact 130

Dr. David Brookstein provided two different and consistent analyses as to why FiberWire's ultra high molecular weight PE is equivalent to the claimed first-fiber forming materials (Mitek Ex. 3 at ¶¶16-34).

Mitek Fact 131

Dr. Brookstein opined that any differences between FiberWire's ultra high molecular weight PE and the claimed first fiber-forming materials are insubstantial because FiberWire's PE is consistent with the description of the preferred embodiments of the first fiber-forming materials in the 446 Patent (Mitek Ex. 3 at ¶17).

Mitek Fact 132

The 446 patent describes the preferred embodiments of the first fiber-forming materials as "lubricating yarns," "nonabsorbable polymers," and "fiber-forming materials" (*id.*).

Mitek Fact 133

Dr. Brookstein pointed out that FiberWire's PE is a lubricous, non absorbable, and fiber-forming material and concluded that differences between FiberWire's PE and the recited first fiber forming materials are therefore insubstantial (Mitek Ex. 3 at ¶¶16-17).

Mitek Fact 134

Dr. Mukherjee agrees that FiberWire's PE is lubricous and fiber-forming (Mitek Ex. 6 at 239:10-13; 296:4-6; 296:14-16).

Mitek Fact 135

FiberWire's PE is not bioabsorbable (Arthrex Ex. 14).

Mitek Fact 136

As Dr. Brookstein explained, the 446 patent describes embodiments in which PE is braided with PET, the PE is a lubricating yarn, and the PET improves strength of the heterogeneous braid (Mitek Ex. 3 at ¶20).

Mitek Fact 137

FiberWire is a braid of PE witih PET, the PE is lubricous, and the PET imparts strength (namely at least knot holding strength)[1] to the heterogeneous braid (*id.*).

Mitek Fact 138

Dr. Brookstein's opinion is supported by the testimony of Mr. Grafton, who was Arthrex's Vice President of Engineering and the alleged designer of FiberWire (Mitek Ex. 1 at 40:15-19; 44:5-7).

Mitek Fact 139

Mr. Grafton testified that, originally, Arthrex had considered a 100% ultra high molecular weight PE braid (Mitek Ex. 1 at 45-46).

Mitek Fact 140

But Mr. Grafton found this braid unacceptable because it was too lubricous and weak; it would not hold a knot (Mitek Ex. 3 at ¶18).

Mitek Fact 141

Arthrex discarded the idea of using PE until Mr. Grafton thought of braiding PET with the lubricous PE, so that the PET could impart knot holding strength to the braid and overcome the lubricous PE's disadvantages (*id.*).

Mitek Fact 142

Mr. Grafton's testimony about the development of FiberWire underscores that FiberWire is a braid of a lubricious first fiber-forming material with a second fiber-forming material to impart braid strength, like certain of the preferred embodiments in the 446 Patent (Arthrex Ex. 3 at 4:9-40).

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[1] Knot holding strength is a recognized suture strength property and is the force at which a knot fails by slipping, elongating to a certain extent, or breaking (Mitek Ex. 3 at ¶20).

Mitek Fact 143

Arthrex admitted in its U.S. Patent No. 6,716,234 that ultra high molecular weight PE "does not have acceptable knot tie down characteristics for use in surgical applications" (Mitek Ex. 3 at ¶20).

Mitek Fact 144

Mr. Grafton, a named inventor of the 234 patent, testified that knot tie down as that term is used in his patent is closely related to knot strength and is a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (*id.*).

Mitek Fact 145

According to Arthrex's 234 patent, this deficiency was overcome by braiding the lubricous PE with polyester or PET (Mitek Ex. 2 at 2:50-57).

Mitek Fact 146

Dr. Brookstein provided a function/way/result analysis in support of his opinion that the differences between ultra high molecular weight PE and the recited first fiber-forming materials are insubstantial (Mitek Ex. 3 at ¶¶21-34).

Mitek Fact 147

The function of the first fiber-forming materials is to contribute a property that is different than a yarn from the claimed second set of materials (Mitek Ex. 3 at ¶¶23-25).

Mitek Fact 148

The "way" the claimed first fiber-forming materials perform their function is to have "at least one yarn from the first set of yarns in direct intertwining contact with at least one yarn from the second set" (Mitek Ex. 3. at ¶26).

Mitek Fact 149

The "result" was "to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that, when they are braided, the yarns contribute to the properties of the overall heterogeneous braid" (Mitek Ex. 3 at ¶30).

Mitek Fact 150

FiberWire's braided PE performs these functions and obtains the same result in the same way as the recited first fiber-forming materials because it contributes lubricity and strength properties that are different than the second fiber-forming material, PET, and is braided in direct intertwining contact with at least one PET yarn (Mitek Ex. 3 at ¶¶23-34).

<u>Mitek Fact 151</u>

Dr. Mukerjee admitted that FiberWire's PE is lubricous (Mitek Ex. 6 at 239:10-13; 296:4-6; 296:14-16).

<u>Mitek Fact 152</u>

The 446 Patent states "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which makeup the yarns" (Arthrex Ex. 8 at 2:49-52).

<u>Mitek Fact 153</u>

The 446 Patent states "it is possible to tailor the physical . . . properties of the braid by varying the type and proportion of each of the dissimilar fiber forming used" (*id.* at 2:58-62).

<u>Mitek Fact 154</u>

The 446 Patent states in ***preferred embodiments*** the first fiber-forming materials can contribute other properties including "pliability," "compliance" and "surface lubricity" (*id.* at 4:11-13, emphasis added).

<u>Mitek Fact 155</u>

The sentence on which Arthrex relies (the sentence referenced in Mitek Fact 154) refers not only to pliability but also *compliance and surface lubricity* (*id.* at 4:12-13).

<u>Mitek Fact 156</u>

The properties in the sentence referenced in Mitek Fact 154 are for "preferred embodiments," not the invention as a whole (*id.* at 4:11).

<u>Mitek Fact 157</u>

The 446 Patent states "[i]f fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable" (*id.* at 2:22-25).

<u>Mitek Fact 158</u>

The 446 patent does not say that all braids made from all of the first fiber forming materials are all necessarily highly pliable or that the materials used to make the braids are "weak" (Mitek Ex. 5 at ¶¶49-51).

<u>Mitek Fact 159</u>

The first fiber-forming materials are never described in the 446 Patent as "weak" (Mitek Ex. 3. at ¶36).

Mitek Fact 160

PVDF and polypropylene (PP), which are among the materials listed in the group of first fiber-forming materials, are not "weak" (Mitek Ex. 3. at ¶¶36,37).

Mitek Fact 161

Like polyethylene, polypropylene is also available in an ultra high molecular weight form (Mitek Ex. 3 at Ex. 11).

Mitek Fact 162

Ultra high molecular weight PE is "weak" in at least two ways, knot holding properties and compression (Mitek Ex. 3 at ¶39) and some braids of ultra high molecular weight PE are weak (*see supra*).

Mitek Fact 163

FiberWire's PE is lubricous, while FiberWire's PET has a different lubricity (Mitek Ex. 3. at ¶¶17, 25).

Mitek Fact 164

FiberWire contributes to braid pliability because its lubricity allows the fibers and yarns to slide past each other when FiberWire bends (Mitek Ex. 3 at ¶40).

Mitek Fact 165

As the 446 Patent explains, material lubricity permits fiber-to-fiber mobility, so that when the braid is bent, the fibers can easily bend and slide past other fibers (Mitek Ex. 3. at ¶41).

Mitek Fact 166

Ultra high molecular weight PE has many purposes, it provides braid lubricity, surface properties, handleability properties, tensile strength, and detracts from knot holding strength (Mitek Ex. 3 at ¶40).

Mitek Fact 167

Dr. Burks is an experienced orthopedic surgeon (Mitek Ex. 9 at 11:24-17:17).

Mitek Fact 168

Dr. Burks allegedly conducted a blind test, including a knot tie down/handleability test, of uncoated and coated FiberWire for Arthrex and at his deposition (*id.* at 70:7-72:23; 91:20-99:6).

Mitek Fact 169

After examining the samples, Dr. Burks twice testified that the differences between the coated and uncoated samples were “subtle” (Mitek Ex., 9 at 87:7-13; 88:1-3; 96:18-19; 98:19-25); the coated and uncoated sutures were “pretty close” (*id.* at 88:1-3); and he “could not clearly feel a difference” between the two sutures (*id.* at 88:9-10).

Mitek Fact 170

Dr. Burks testified:

Q. How would you qualify the difference that you just observed, based on your test?

A. When you say "qualify" are you asking for like an amount?

Q. How would you characterize the difference between the sutures?

A. *Well the difference is, I think, subtle and there's no doubt in my mind that I could line up, you know, a hundred sutures and have error* where I would say, you know, I think this one is one way or the other and make a mistake. *So there's certainly not enough difference to clearly say that I know every time exactly how that feels.*

(*id.* at 97:15-98:3) (emphasis added).

Mitek Fact 171

Surgeons normally handle FiberWire in the surgical environment while wearing gloves (*id.* at 51:12-14).

Mitek Fact 172

When Dr. Burks conducted the blind test for Arthrex, he admitted that he may not have been able to tell a difference if he had not had his gloves off (*id.* at 73:9-14; *see also* 96:24-97:5).

Mitek Fact 173

Dr. Burks testified that

Q. Did using gloves in the tests in Exhibit 232 affect your ability to distinguish between suture A and suture B?

A. I think, clearly, using gloves makes the feel of the suture a little different. I guess I can't answer directly to say if it makes the difference but, yes, it probably makes a difference.

Q. What difference does it make?

A. You are covering your skin with the gloves, so, you know, as you feel suture, your absolute sensation of the suture probably changes some.

Q. Could you have reached the same conclusions you reached in Exhibit 232 if you solely used gloves in performing the tests?

A. I didn't do it that way, so I guess I can't answer that and say yes or no.

Q. Did not using gloves help you to distinguish between suture A and suture B?

A. Potentially, yes

(*id.*at 72:4-23).

Mitek Fact 174

FiberWire's coating is just silicone applied thinly to the braided suture as a surface lubricant as opposed to a monofilament-like coating which would materially affect fiber-to-fiber mobility (Mitek Ex. 3 at ¶47).

Mitek Fact 175

Dr. Brookstein confirmed that the silicone coating on FiberWire is present in small amounts and does not substantially penetrate the braid and create a monofilament like structure (*id.*).

Mitek Fact 176

Regardless of FiberWire's coating, FiberWire is still "two dissimilar yarns braided together to achieve improved handleability or pliability without significantly sacrificing its physical properties" (*id.*).

Mitek Fact 177

FiberWire has a very specific silicone coating that is applied to its surface (*id.*).

Mitek Fact 178

The 446 Patent specification defines coatings as optional or immaterial:

> *If desired*, the surface of the heterogeneous multifilament braid can be coated . . . to further improve handleability and knot tiedown performance of the braid.

(Arthrex Ex. 8 at 6:5-8) (emphasis added).

Mitek Fact 179

The 446 Patent specification draws a distinction between surface coatings, like FiberWire's, which do not significantly affect fiber-to-fiber mobility, and heavy coatings that significantly restrict fiber-to-fiber mobility and form monofilament-like structures (*id.* at 6:11-13; 8:50-61).

Mitek Fact 180

Dr. Brookstein's affidavit and testimony from Dr. Mukherjee, establishing that the coating on FiberWire does not materially affect its novel and basic characteristics, as they are defined by Mitek, are of record (Mitek Ex. 3 at ¶¶43-54; Mitek Ex. 6 at 562:20-25).

Mitek Fact 181

In 2001, Arthrex applied for a patent related to its FiberWire product (Mitek Ex. 2).

Mitek Fact 182

The Patent Office rejected Arthrex's claims over the 575 Patent (Mitek Ex. 5 at Ex. 3).

Mitek Fact 183

In response to that rejection, Arthrex argued that the 575 Patent "*does not disclose* an example of a braided sheath that includes a blend of both ultra high molecular weight polyethylene and polyester" (or PET) (*id.* at DMI041091) (emphasis added).

Mitek Fact 184

Arthrex and Dr. Mukehrjee admit that polyester includes PET (Arthrex Br. at 26).

Mitek Fact 185

Dr. Mukherjee testified that:

> Q. -- it says, the second sentence says, "As noted above, Chesterfield, et al., '575, does not disclose an example of a braided sheath that includes a blend of both -- of both ultra high molecular weight polyethylene and polyester."
>
> Do you see that?
>
> A. Yes.
>
> Q. Do you agree with that statement?
>
> A. Yes.

(Mitek Ex. 6 at 183:9-15).

Mitek Fact 186

The 575 Patent discloses that the spiroid braid of Figures 6 is comprised of a high molecular weight, high strength material and a bioabsorbable material (Mitek Ex. 5 at Ex. 2 at 4:11-13).

Mitek Fact 187

Even if the high molecular weight, high strength material in the spiroid braid of Figure 6 of the 575 Patent is understood to be ultra high molecular weight PE – one of the first fiber-

forming materials recited in the 446 Patent claims – there is no disclosure in the patent that the *second* material in the structure is one of the materials required by the claims, namely, PET, nylon or aramid (non-bioabsorbable materials) (Mitek Ex. 5 at 15-16).

Mitek Fact 188

The *claims* of the 575 Patent claims describe use of a sternum closure ribbon or tape, not a suture (Mitek Ex. 5 at ¶22).

Mitek Fact 189

Arthrex's counsel, Mr. Soffen, advised Arthrex that the 575 Patent claims do not describe the use of a suture (Mitek Ex. 12).

Mitek Fact 190

Claim 12 is directed to a method for repairing split portions of body tissue (Mitek Ex. 5 at ¶22).

Mitek Fact 191

The 575 Patent claims do not describe PE braided in direct intertwining contact with a polyester (Mitek Ex. 5 at ¶21-25).

Mitek Fact 192

Although claim 12 refers to polyester, it does not expressly specify how the polyester fibers are braided with the claimed first fibers of PE (*id.* at ¶21).

Mitek Fact 193

The 575 Patent claims merely recited a "braided" construction which could be a construction, such as a core-sheath arrangement as described in Figures 8 and 9, which is not a "direct intertwining contact" construction (*id.*).

Mitek Fact 194

The 446 Patent claims recite that the surgical suture is composed of "discrete yarns in a *sterilized*, braided construction." (Arthrex Ex. 8 at 8:65-66).

Mitek Fact 195

Claim 9 of the 446 Patent recites that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (*id.* at 9-11).

Mitek Fact 196

There is no disclosure in the 575 Patent of the recited volume fraction of claim 9 of the 446 Patent (Mitek Ex. 5 at ¶¶27-29).

Mitek Fact 197

Dr. Steckel testified, and his notebook confirms, that the invention of the 446 Patent was conceived of at least as early as June 1988, and that sutures were made and tested as least as early as February 1989 (Mitek Ex. 5 at ¶¶33-35).

Mitek Fact 198

Sterilization is a well known, commercialization step in suture development (Mitek Ex. 5 at ¶¶40-42).

Mitek Fact 199

Dr. Mukerjee testified that sterilization of suture materials was well-known at the time of the invention (Mitek Ex. 6 at 550:8- 551:1).

Mitek Fact 200

Dr. Steckel would only have sterilized if he intended to use the sutures in human surgery or to commercialize the invention (Mitek Ex. 5 at ¶¶41-42).

Mitek Fact 201

The 446 Patent inventors conceived of the invention at least as early as June 1988 (Mitek Ex. 5 at ¶33).

Mitek Fact 202

A memorandum from Mr. Goodwin, the attorney who prepared the application, and Dr. Steckel's testimony show that a draft application was sent to the inventors at least as early as January 1992 (Mitek Ex. 10; Mitek Ex. 4 at 284:4-17).

Mitek Fact 203

Also, Dr. Steckel's testimony and Mr. Goodwin's memorandum show that Mr. Goodwin finalized the application by trying to obtain comments from Dr. Steckel and contacting his supervisor when Dr. Steckel did not respond while he was in the process of moving from New Jersey to Ohio in January 1992 (Mitek Ex. 10 &11; Mitek Ex. 4 at 284:4-287:10).

Mitek Fact 204

Dr. Steckel's testimony further shows that he reviewed at least two draft applications, had email communications and discussions with counsel before the application for the 446 was filed, collected comments from the inventors, and finalized the application after completing his January move from New Jersey to Ohio in February 1992 (*id.* at 48:9-20; 264:19-271:23; 275:2-10; 276:4-281:25; 284:4-287:10).

<u>Mitek Fact 205</u>

According to Dr Mukherjee, "the function performed by the first fiber-forming materials is to add lubricity with the recognition that these materials will detract from the strength of the resulting suture" (Mitek Ex. 13).

<u>Mitek Fact 206</u>

The 446 Patent states that "highly pliable braids *can* be prepared," but that does not mean that *all braids* made from the materials are highly pliable because they can have different stiffness characteristics or be heat treated or processed in different ways to make the braids less pliable (Mitek Ex. 5 at ¶59).

<u>Mitek Fact 207</u>

Col. 2, line 24 states that "*in most cases,*" not all cases, these braids will be relatively weak (*id.*).

<u>Mitek Fact 208</u>

Col. 2, line 24-25 only refers to some *braids* as being weak, not the braided *materials* as being weak, as Arthrex incorrectly suggests (*id.*).

<u>Mitek Fact 209</u>

The 446 Patent says it would be *desirable* to form a braid with "enhanced pliability . . . without appreciably sacrificing physical properties," this is just one possible goal of the invention (Mitek Ex. 3 at ¶35; Mitek Ex. 5 at ¶50).

<u>Mitek Fact 210</u>

FiberWire's PE *does* detract from strength and *does* improve braid pliability (Mitek Ex. 3 at ¶¶18-20, 40).

<u>Mitek Fact 211</u>

Fiber *material* stiffness is a property dependent upon just the material properties and cross sectional shape of the specimen (Mitek Ex. 3 at ¶41).

<u>Mitek Fact 212</u>

Braid stiffness is dependent upon many parameters, including not only the stiffness of the braided materials, but also the manner in which they are braided, and, importantly, material lubricity (Mitek Ex. 3 at ¶41).

Mitek Fact 213

The 446 Patent inventors conceived of the invention at least as early as June 1988 (Mitek Ex. 5 at ¶33).

Mitek Fact 214

The 446 invention was constructively reduced to practice when the application for the 446 Patent was filed on February 19, 1992 (Arthrex Ex. 8).

Respectfully submitted,

Dated: September 1, 2006

DEPUY MITEK, INC.,
By its attorneys,
_/s/ Erich M. Falke_________

Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

Daniel J. Gleason (BBO #194900)
Michelle Chassereau Jackson (BBO #654825)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.

______________________________/

DEPOSITION OF:	DONALD GRAFTON
DATE:	March 14, 2006
TIME:	8:38 a.m. to 1:23 p.m.
LOCATION:	The Ritz Carlton Golf Resort 2600 Tiburon Drive Naples, FL 34112
TAKEN BY:	Plaintiff
REPORTER:	Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER:	Gene Howell, CLVS

26

Q. Let me back up to make sure this is clear. Knot strength versus knot tiedown. In your mind, are they the same thing or are they different?
A. I'm not sure I understand your question. Say that again.
Q. Sure. Knot strength --
A. Mmm-hmm (affirmative).
Q. -- which I think you testified that you understood to be tying a knot in a suture and pulling it on a tensile machine -- tensile tester machine to determine the strength at which the knot will break; right?
A. Yes.
Q. Okay. Then there's another term called knot tiedown, and I'm trying to understand whether, in your mind, you think that's the same as knot strength or do you use that term to mean something else?
A. They're closely related.
Q. And how are they related?
A. When you have a knot tiedown, you've tied a knot. The strength of the knot is going to affect the ability to hold -- to approximate the tissue in the tiedown area that you're talking about.
Q. If the knot had a good tiedown or a bad tiedown, what do you mean by that?

27

A. Its ability to approximate the tissue and hold it in place through biomechanical forces.
Q. So that's related to knot strength, but it's not necessarily the same thing; is that the way you're using the term?
A. Yes.
Q. The way I heard you describe knot tiedown was you said the ability to approximate the tissue and hold it into place through biomechanical forces.
A. (Witness nods head affirmatively).
Q. When you say ability to approximate the tissue, what do you mean by that?
A. Shift tissue in the position that the surgeon would like for it to be on the bone.
Q. Shift tissue; did you say?
A. Yes.
Q. S-H-I-F-T?
A. Yes.
Q. So the knot's moving the tissue?
A. The suture is holding -- the suture loop with the knot in it, is holding the tissue in the position that the surgeon would like for it to be on bone.
Q. That's taking the place of the tissue? When you say approximate the tissue, how is it approximating tissue?

28

A. It's -- The tissue is here. The location the surgeon wants it here. The suture loop as it is tied moves the tissue into position.
Q. Holds it there?
A. Yes.
Q. And what -- what biomechanical forces were you referring to?
A. Forces on the glenohumeral joint.
Q. In a knot strength test, it's the forces are being applied and generally in one direction; correct?
A. Yes.
Q. The biomechanical force that you are referring to in this knot tiedown, the forces are coming from different directions; right?
A. Yes.
Q. Okay. When you are referring to knot tiedown then, you're referring to -- you're referring to it in a sense as a strength?
A. Are you finished? Is that the question?
Q. Right.
A. I don't believe -- Say it again then.
Q. Sure. Knot tiedown, the way you're referring to it, it's a strength then? It's kind of like -- because knot strength would be measured in p.s.i.
A. I said that's one of the attributes of it.

29

That's not the total attribute of it. I mean it's to approximate tissue into position is knot tiedown.
Q. Well, what else would be included?
A. I just told you. Approximate tissue, strength.
Q. So the strength would -- I understand the --
A. The size of the knot bundle. You know, there's --
Q. Size of the knot bundle?
A. Yes.
Q. What do you mean by that?
A. How large the knot is once it has been tied and cut.
Q. So knot tiedown includes the size of the knot bundle?
A. Yes. You know, the knot tiedown -- I want to say this -- that's not a term that we specifically use, so it's a little bit foreign. I mean I don't -- I've never had a surgeon ask me about knot tiedown.
Q. Okay.
A. So I didn't -- your -- I'm not sure where you're going with this, but there's -- we did knot testing and we did straight pull testing of the suture so that your knot tiedown, I'm -- I'm not real sure what you're asking for there. I --
Q. Well --

38

Q. And do you know how many yarns were used in the polyester?
A. No.
Q. No?
A. No.
Q. Okay. How about the Tevdek suture? Was that made on a carrier braider?
A. Yes.
Q. Do you know how many yarns were used in the Tevdek suture?
A. No.
Q. Was the polyester suture from Pearsalls, was that, after it was braided, was it heated up and melted together?
A. I don't know.
Q. Okay. How about the Tevdek suture? Was that heated up --
A. I don't know.
Q. -- and melted together?
A. Do not know.
Q. After -- Let me back up. Any problems with the Tevdek suture?
A. Yes.
Q. What were the problems with the Tevdek suture?
A. Tensile strength was low.

39

Q. Any others?
A. That's enough.
Q. Okay. Were there --
A. That will kill the product.
Q. Okay.
A. Others were -- the others were insignificant, if there were some. That killed the product.
Q. That killed the product?
A. Yes.
Q. Okay. How about the knot strength of the Tevdek suture? Was that low?
A. If your tensile strength is low, sir, we're talking about straight pull, knot pull, that would cover both categories.
Q. Okay. So the knot strength of the Tevdek suture was low, too?
A. Yes.
Q. So that was part of the reason why the Tevdek suture was killed? Is that the word?
A. Yes.
Q. How about the knot tiedown Tevdek suture? How was that?
A. I have already been through that with you. We tested for tensile strength in knot and straight pull; okay? So to answer your question, if those two were low,

40

then -- then you would expect the knot tiedown, the term you have been using, to also be low.
Q. If the knot strength and tensile strength are low, you expect the knot tiedown to be low?
A. Yes.
Q. If the knot tiedown's low, do you expect the knot strength to be low?
A. Don't know.
Q. Is it -- Were these complaints from surgeons about the Tevdek suture, about the strength?
A. That's correct.
Q. And is that when the development of FiberWire began?
A. Yes.
Q. Let me back up. When you started with Arthrex, what was your position?
A. Vice President of Engineering.
Q. And how long did you hold that position?
A. Total time I was there.
Q. And when you started at Arthrex, how many people reported to you?
A. Zero.
Q. And when you left Arthrex, how many people reported to you?
A. Approximately 15. I'm not sure.

41

Q. So after Arthrex, have you been employed?
A. No.
Q. And you left Arthrex when?
A. January of 2005.
Q. I will show you DePuy Mitek Exhibit 129. This is Defendant Pearsalls, Limited's Initial Disclosures in this case. Under the first section, A, it says, "Individuals likely to have discoverable information that Pearsalls may use to support its claims or defenses." And the first person listed is Mr. Reinhold Schmieding. Do you see that?
A. Yes.
Q. Then if you turn to the second page, the second person listed is you. Do you see that?
A. Yes.
Q. It says that you are familiar with the development, marketing and sales of Arthrex's FiberWire, surgical suture products, and decisions about offering those products into the market." Do you see that?
A. Yes, I do.
Q. Do you agree with that?
A. Yes.
Q. It says, "Mr. Grafton is familiar with the state-of-the-art for surgical suture products." Do you see that?

A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they

compared to the competitive products.
Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength

and tensile strength; right?
A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr.

Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."
And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

46

A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

47

Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is

48

processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had

49

this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

50

ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes.
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

51

Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

52

Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent, I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

53

A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

58

done on any product. Obviously, there needed to be a check -- there's a checklist -- okay -- so I'm going by memory, that it needed to be looked at from a patent standpoint to see if there was any infringing as well as whether the product was compatible, along with the GNP items that are required for the product.

Q. Okay. Those things you are describing to me, those were all kind of commercial considerations. My question is a little different. Maybe my question wasn't clear. My question was more along the lines of once you had the prototype of the ultra-high molecular weight polyethylene and PET braided together and you tested it and you believed that it would work as a suture, I understand there's things you needed to do to make it a commercial product.

Was there anything else you needed to do in your mind to clarify whether it needed to -- whether it could work as a suture?

A. We needed to have a surgeon look at it that would actually be tying knots with it to get their understanding of -- of how they felt about the suture.

Q. Okay. Anything else though?

A. Not that I recall.

Q. Okay.

MR. SOFFEN: Is it time for a break? In a few

59

minutes?

MR. BONELLA: Yeah. Just give me five. Let me just finish this line of questions.

Q. Was the initial prototype that was ultra-high molecular weight polyethylene, was that sterile?

A. I don't remember.

Q. How about the prototype that was PET and ultra-high molecular weight polyethylene braided together? Was that sterile?

A. I don't remember.

Q. Would it have to have been sterile? Would the prototypes have to have been sterile?

A. Not to test on the tensile test machine.

Q. Why not?

A. Because it's not going into a human. You don't -- The bioburden levels at that point is not a factor that was wrong.

Q. Was sterilization another process at that time? Was that something you really didn't have to account for?

A. Say the question again.

Q. I'm just making sure that what you're saying is that sterilization is just to -- was just to -- it's really for biocompatibility? It's not to change the properties of the material; is that right?

MR. SOFFEN: Objection; vague.

60

A. I don't know. I don't know. That's really a weird question.

Q. I understand you are saying they weren't sterile.

A. No. I didn't say -- I said I don't recall, sir.

Q. You don't recall?

A. Yes.

Q. Okay. And my question was would they have had to have been, and you said, I think, no because they were testing them for mechanical properties.

A. Yes.

Q. Okay. Did you -- Would the sutures have had to have been sterile when you tested them for mechanical properties?

A. I already answered that.

MR. SOFFEN: Objection; asked and answered.

A. I said no. It didn't have to be to be tested on a tensile test machine.

Q. And why is that?

A. I already answered that also. It's not being used for human or animal use, so the biocompatibility issues of the suture at that time were not looked at. The mechanical features of the suture were all that were looked at at that portion of the prototype stage.

Q. Did sterilization have a big effect on the mechanical properties of the suture, the tensile?

61

MR. SOFFEN: Objection.

A. I -- I can't answer that question.

Q. You don't know?

A. No.

Q. But when you made the decision to go forward with this, you can't remember whether they were sterile or not?

A. You asked me -- You're -- you're kind of putting a couple of things together, so that's why you're --

Q. Okay. Maybe I'm getting confused.

A. You asked me if the prototypes were sterile, and I said no.

Q. Okay.

A. The decision to go forward with the product, obviously, there has to be sterilization done before the product can be marketed.

Q. Absolutely. And are you saying that the decision to go forward with it was made before you tested a sterile product?

A. I can't say that.

Q. Do you recall testing a sterile product before the decision was decided to make -- decided to go forward with the PET and the --

A. I don't remember.

Q. -- ultra-high molecular weight polyethylene?

A. I don't -- It depends on what point in time you

US006716234B2

(12) **United States Patent**
Grafton et al.

(10) **Patent No.: US 6,716,234 B2**
(45) **Date of Patent: Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

(75) Inventors: **R. Donald Grafton**, Naples, FL (US); **D. Lawson Lyon**, Exeter (GB); **Brian Hallet**, Taunton (GB)

(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

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(22) Filed: **Sep. 13, 2001**

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(51) **Int. Cl.**7 .... **A61L 17/04**
(52) **U.S. Cl.** **606/228**
(58) **Field of Search** 606/228

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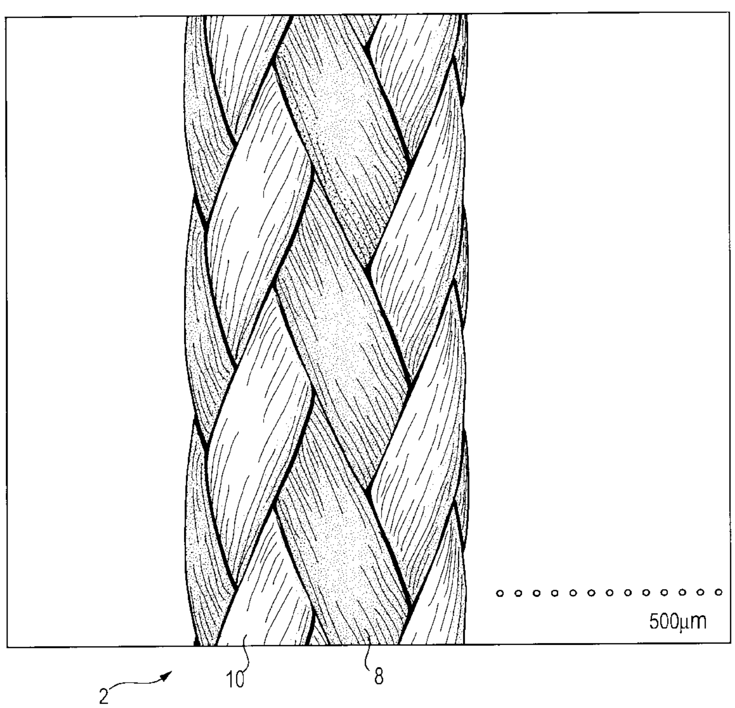
Primary Examiner—David O. Reip
(74) *Attorney, Agent, or Firm*—Dickstein Shapiro Morin & Oshinsky, LLP

(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets



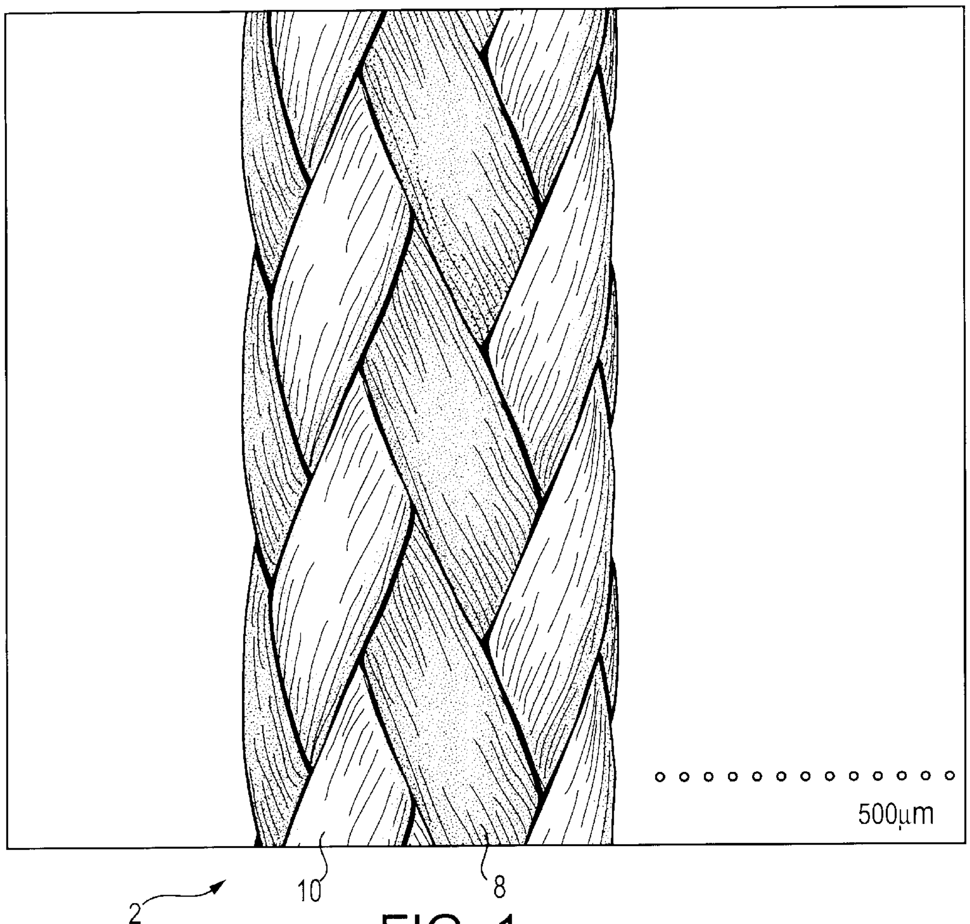


FIG. 1

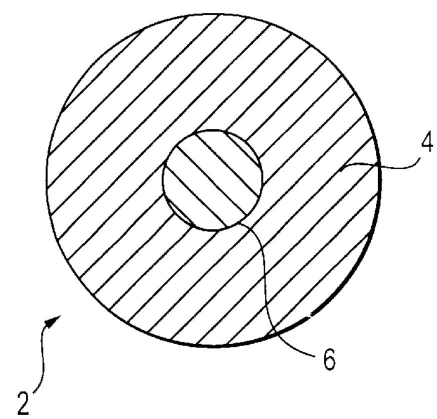


FIG. 2

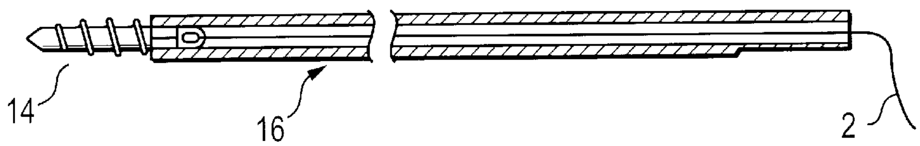


FIG. 3

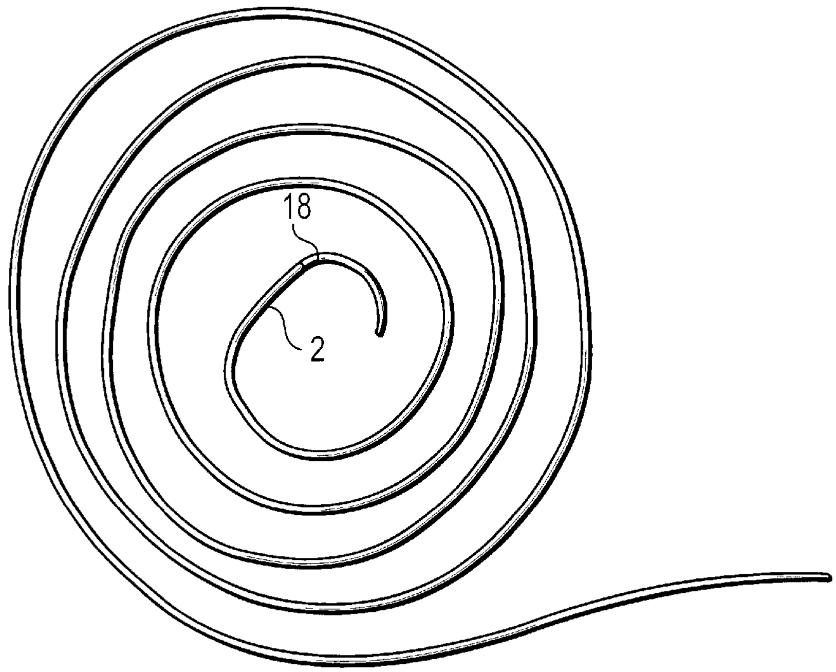


FIG. 4A

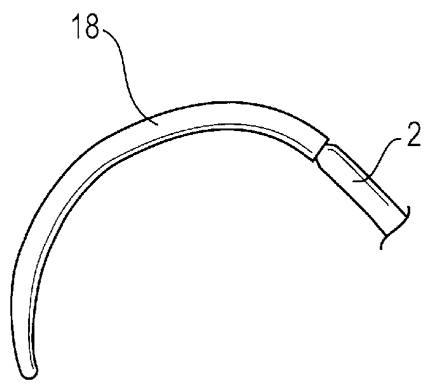


FIG. 4B

HIGH STRENGTH SUTURE MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. **1** is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. **2** is a schematic cross section of a length of suture according to the present invention.

FIG. **3** is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. **4**A and **4**B show the suture of the present invention attached to a half round, tapered needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, a scanning electron micrograph of a length of suture **2** according to the present invention is shown. Suture **2** is made up of a cover **4** and a core **6** surrounded by the cover. See FIG. **2**. Strands of ultrahigh molecular weight polyethylene (UHMWPE) **8**, sold under the tradename Dyneema or Spectra, and strands of polyester **10** are braided together to form the cover **4**. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture **2** is attached to a suture anchor **14** as shown in FIG. **3** (prepackaged sterile with an inserter **16**), or is attached to a half round, tapered needle **18** as shown in FIGS. **4**A and **4**B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim **1**, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim **1**, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim **1**, wherein the core comprises a bout 30% of the filament.

5. The suture filament of claim **1**, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim **1**, further comprising a coating disposed on the cover.

7. The suture filament of claim **1**, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	**)** **)** **)** **)** **)** **)** **)** **)** **)** **)** **)** **)** **)** **)** **)**	**Civil No. 04-12457 PBS**

Declaration of Dr. David Brookstein In Support of DePuy Mitek's
<u>Claim Interpretation of the Hunter Patent and Summary Judgment of Infringement</u>

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and conducted research in

the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

B. Work Experience

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

C. Education

6. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

7. I have a Master of Science in Textile Technology from M.I.T., 1973.

8. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

9. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

10. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based,

resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

11. My publications and patents for which I am an inventor are listed in my curriculum vitae (Ex. 1).

12. I have been asked to prepare this declaration based on my prior reports, deposition testimony, and Arthrex's motion for summary judgment. This declaration is basically my prior opinions reformatted to address the issues that I have been asked to address.[1]

II. Legal Framework of My Opinions

13. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

14. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

15. Infringement is "literal" when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still

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[1] For purposes of this declaration, I use the term FiberWire to refer to Arthrex's FiberWire and TigerWire's products except where noted.

infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused device "performs substantially the same function in substantially the same way to obtain the same result" ("function/way/result test") as the claimed element.

III. If "General Purpose PE" Is Deemed Not To Literally Include FiberWire's Braided PE, Then FiberWire Infringes Under the Doctrine of Equivalents

A. The Differences Between FiberWire's PE and the Claimed First Fiber-Forming Materials Are Insubstantial

16. If "PE" as claimed in the 446 Patent is construed to mean "general purpose PE" (Arthrex Brf. on Claim Construction at 10, hereinafter "Arthrex Br."), and it is found that FiberWire's braided PE is not literally "general purpose PE," then it is my opinion that there is infringement under the doctrine of equivalents because the differences between FiberWire's braided PE and the first fiber-forming materials are insubstantial.

17. In a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting "as lubricating yarns" (Ex. 2 at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. 3 at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be "non-absorbable polymers" (Ex. 2 at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. 2 at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent's description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56.

18. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. 3 at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (*id*. at 51:15-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (*id*. at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (*id*. at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (*id*. at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. This just like the 446 Patent because the 446 Patent describes embodiments in which the first fiber-forming materials are lubricous and the second fiber-forming materials impart strength. Accordingly, FiberWire's braid is not, as Arthrex has suggested, the opposite of what is described in the 446 Patent.

19. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 4 at 1:19-21; Ex. 3 at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. 3 at 26:24-27:6). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength. According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with

polyester (Ex. 4 at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the "ability to approximate the tissue and hold it in place through biomechanical forces" (Ex. 3 at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester. Thus, Arthrex's 234 Patent further shows that the differences are insubstantial because UHMWPE is described as a lubricous yarn that with bad knot properties, and similarly embodiments of the first fiber-forming materials are described as lubricous.

20. I understand that Arthrex has asserted that the differences between the first fiber-forming materials (if PE does not include UHMWPE) and UHMWPE are substantial because the purpose of UHMWPE in FiberWire is alleged to be to provide strength (Arthrex Br. at 11). I disagree with this statement because the 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. 2 at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. 3 at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. 2 at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. 3 at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,[2] of

[2] I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test. I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Exs. 26 and 27. Knot holding strength is an indication

the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot. Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

B. The Differences Between the Claimed First Fiber-Forming Materials And FiberWire's PE Are Insubstantial Based On the Function/Way/Result Analysis

21. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial under the function/way/result analysis.

22. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

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of knot security. The 446 Patent describes another exemplary knot security test (Ex. 2 at 6:36-44).

23. In my opinion, the "function" of the first fiber-forming material is the same as the function of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**Function of Limitation Under the Doctrine of Equivalents**	**Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

24. My opinion regarding the "function" of the first fiber-forming material is supported by the '446 Patent. The '446 Patent explains that the first fiber forming material is "dissimilar" to the second fiber and the braid of dissimilar yarns provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 2 at 2:50-52; 3:43-48). Further, the '446 Patent explains that it is possible to "tailor the physical" properties by "varying the type and proportion of each of the dissimilar fiber forming materials used" (*id*. at 2:58-61). Also, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (*id*. at 8:19-21).

25. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid.

Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Ex. 5 at 306:17-307:14; Ex. 6; *see also* Ex. 5 at 307:15-308:14; Ex. 7). Further, as I explained in my rebuttal report with respect to Mr. Grafton's work and Arthrex's 234 Patent, FiberWire's PE also provides lubricity and other surface properties that are different than PET, and PET when braided with PE in FiberWire increases the knot holding strength.

26. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Way" of Limitation Under the Doctrine of Equivalents**	**Way UHMWPE performs its Function in FiberWire™ and TigerWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Ex. 8 at 99-107).

27. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct intertwining contact" with a yarn from the second set (Ex. 2 at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (*id*. at 2:56-58; 3:43-48). Also, during the

prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct "intertwining" contact of dissimilar yarns (Ex. 9 at 2, emphasis original).

28. Further, the '446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Ex. 2 at 4:9-59). The '446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (*id*. at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials, so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these "preferred embodiments," and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

29. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products have the same "way" as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex's FiberWire™ and TigerWire™ products is braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Ex. 8 at p. 99-107).

30. In my opinion, the "result" of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Result" of Limitation Under the Doctrine of Equivalents**	**Result of UHMWPE in FiberWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

31. My opinion regarding the "result" of the first-forming material is supported by the '446 Patent. For example, the '446 Patent explains that the "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials" (Ex. 2 at 2:49-52). Further, the '446 Patent states that the "types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties." (*id*. at 6:52-56).

32. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. In FiberWire™, when the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET. Also, as I explained in my rebuttal report and through my declaration with reference to Arthrex's 234 Patent, Mr.

Graftons' work, and the development of FiberWire, UHMWPE adds lubricity, pliability, and surface properties that are different than PET.

33. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

> Q What did you understand Mr. Grafton to mean when he said:
> "Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible". What did you understand that to mean?
> A Yes, that he wanted a braid which was more -- not so stiff.
> Q As the 100% ultra high molecular weight polyethylene?
> A Yes. (Ex. 5 at 306:20-307:4, Ex. 6)

> Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?
> A Yes. (Ex. 5 at 307:10-14, Ex. 6).

34. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Ex. 2 at 2:58-61).

C. I Disagree With Arthrex's Assertions Regarding the Purpose & Function of the First Fiber-Forming Materials

1. The 446 Patent Does Not State that the Only Function of the First Fiber-Forming Materials Is to Improve Pliability

35. I disagree with Arthrex's assertion that the only function of the first fiber-forming materials described in the 446 Patent is improving pliability. As I explained in my first report at ¶55 and my rebuttal report at ¶10, the 446 Patent describes a broader function for the first fiber-forming materials that is not limited:

- "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which makeup the yarns" (*id.* at 2:49-52);
- "it is possible to tailor the physical . . . properties of the braid by varying the type and proportion of each of the dissimilar fiber forming used" (*id.* at 2:58-62);
- in preferred embodiments the first fiber-forming materials can contribute other properties including "pliability," "compliance" and "surface lubricity" (*id.* at 4:11-13).

As I explained above, the properties of the first fiber forming materials are much broader than just pliability.

2. The 446 Patent Does Not Describe the First Fiber-Forming Materials As "Relatively Weak"

36. I disagree with Arthrex's assertion that the 446 Patent describes the first fiber-forming materials as "relatively weak," (Arthrex Br. at 11) and that this is a basis for finding that the differences between the first fiber-forming materials and FiberWire's braided PE are substantial. I disagree because the 446 Patent does not describe the first fiber-forming materials as "relatively weak." For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks' Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd (Ex. 10). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. 11 at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 $mNtex^{-1}$ (Ex. 12). Thus, certain polyethylene and polypropylene fibers are not "weak"

in tensile strength. Thus, I disagree that the 446 Patent describes the first-fiber forming materials as being "weak."

37. Arthrex seems to indicate that the first fiber-forming materials are all necessarily "weak" in tension when compared to the second fiber-forming materials and that only the second set of yarns can impart strength (Arthrex Br. at 11). Even assuming that Arthrex means weak in tension, I disagree with this statement. Arthrex's statement is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks' Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. 10). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 $mNtex^{-1}$ (Ex. 12). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describers the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. 13; *see also* Ex. 14). Consequently, the first fiber-forming materials are not all "weak" in tension in comparison to the second fiber-forming yarns, and it would be incorrect to read the 446 Patent as stating that only the second set of yarns imparts tensile strength, as Arthrex incorrectly suggests.

38. I understand that Arthrex asserts that "the admitted purpose of UHMWPE in FiberWire is to add strength to the braid" and implied that is UHMWPE's only function (Arthrex Br. at 11). I disagree with this assertion because it is an oversimplification and a misunderstanding of the many different properties that a material can provide. As I explained in my rebuttal report at ¶¶24-27 and here above at ¶17, FiberWire's PE is lubricous, and therefore it enhances other FiberWire properties such as handleability, pliability, and surface properties. Arthrex's argument seems to attribute all of FiberWire's strength to FiberWire's PE. I disagree with this assumption. FiberWire's PET also contributes to FiberWire's strength properties, including knot holding strength properties (Ex. 4 at 1:24-26, 29; 2:50-52; Ex. 3 at 103:19-104:15). Further, even if FiberWire's PE's only function is to add tensile strength as Arthrex incorrectly asserts, it is my opinion that the first fiber-forming materials, such as PP and PVDF, function to add tensile strength. Therefore, the differences between UHMWPE and the first fiber-forming materials are insubstantial.

39. Also, Arthrex's assertion that Ultra high molecular weight PE is "strong" is a simplification of material properties. Ultra high molecular weight PE is "weak" in at least two ways, compression and knot holding properties when braided in certain structures, which I explained above with reference to Mr. Grafton's work and Arthrex's 234 Patent. Thus, even if is Arthrex is correct (which it is not) that the 446 Patent describes the first fiber-forming materials as "weak" and braids made from them as weak, ultra high molecular weight PE satisfies these requirements because it too is "weak."

D. Even if Arthrex is Correct Regarding the Teachings Of the 446 Patent, There Is Still Infringement Under the Doctrine of Equivalents

1. Even if Arthrex is Correct That The Function of the First Fiber-Forming Materials Is To Improve Pliability, FiberWire Infringes Because FiberWire's PE Improves Suture Pliability

40. I understand that Arthrex asserts that that the only function of the first fiber-forming materials is to "improve overall pliability of the suture" and FiberWire's PE does not perform this function because it is a stiff material (Arthrex Br. at 10). For the reasons stated above, I disagree that this is the function of the first fiber-forming materials. But even accepting this function, there is still infringement under the doctrine of equivalents because FiberWire's braided ultra high molecular weight PE improves overall pliability of the suture. As I explained in ¶25 of my rebuttal report, ultra high molecular weight PE is lubricous and contributes to braid pliability because it allow the fibers to slide past each other when bent. In constructing FiberWire, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. UHMWPE has many uses. "General purpose" PE and UHMWPE can be substituted for each other, depending on the application.

41. Arthrex's argument appear to be based on confusing two discrete concepts, *material* stiffness and *braid* stiffness. *Material stiffness* is a material property that is dependent upon just the material properties, like the tensile and compressive modulii, and cross-sectional shape of the specimen, which in this instance is a fiber. In contrast, *braid stiffness* for a multifilament

structure like FiberWire is dependent upon many factors including the number of filaments, the modulus of elasticity in tension and compression, the fiber-to-fiber mobility, and the individual moment of inertia of each filament, the manner in which the materials are braided, and material lubricity. As the 446 Patent explains, material lubricity permits fiber-to-fiber mobility, so that when the braid is bent the fibers can easily bend and slide past other fibers. Thus, even accepting that ultra high molecular weight PE is "stiff," Arthrex's counsel assertions that it does not improve overall braid pliability are just wrong.

42. Arthrex's argument is basically the same concept that I addressed before when Arthrex's expert incorrectly assumed that FiberWire is a monofilament structure. As I explained previously, FiberWire is neither a monofilament nor a pure multifilament structure. Arthrex's statement that FiberWire's PE does not improve braid pliability basically makes a similar mistake and incorrectly assumes that FiberWire is a monofilament type structure.

IV. Under Arthrex's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

43. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. I understand that Arthrex contends that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). Arthrex asserts that that FiberWire's coating materially affects this novel and basic characteristic because it materially affects handleabilty and knot tie down properties (Arthrex Br. at 13-14). I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties

described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a "material" affect on the basic and novel characteristics; and (iii) Dr. Burks' tests and analyses show that FiberWire's coating does not materially affect handleability. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

44. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface "lubricant" (Ex. 15).

45. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. 3 at 52:24-53:7). The

homogeneous UHMWPE braid was too lubricous to "hold a knot" (*id*. at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. 3 at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (*id*. at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. 16). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. 16; Ex. 3 at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

Q. And was the knot slippage of this ultra-high
molecular weight polyethylene poor security because of the
lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET
with the ultra-high molecular weight polyethylene to
reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring
to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot
security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent
ultra-high molecular weight polyethylene was poor, the

prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. 3 at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliablity, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

46. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr. Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the [E]thicon sample)" (Ex. 6) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. 6). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

Q. I would like to know what you mean by in your

letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?

A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.

Q. Wait a second. You said optimization of two materials.

A. (Witness nods head affirmatively).

Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?

A. During -- during the -- during that period of time, yes.

Q. So you were balancing off the properties of each material to try to get the optimum properties --

A. Tensile strength.

Q. To get the optimum tensile strength?

A. (Witness nods head affirmatively).

Q. What about knot security?

A. Yes.

Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?

A. Yes.

Q. Any other properties? Knot tiedown?

A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.

Q. So you were varying type and proportion of the materials to optimize all these properties in the product?

A. Yes.

(Ex. 3 at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?

A. All materials used.

(Ex. 17 at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

47. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. 5 at 119:5-9; Ex. 8 at 94:2-9; Ex. 18 at 48:1-50:16; Ex. 19 at ARM002104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters per minute (Ex. 5 at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. 5 at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. 5 at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. 5 at 95:14-17). The process is then repeated. I have measured

[3] Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DMI Exhibits 284, 342, and 285, Exs. 20, 21, and 22, respectively). I determined that the linear density of DMI Ex. 284 (uncoated) is 2393 denier, DMI Ex. 342 (coated once) is 2474 denier, and DMI Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of DMI Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated DMI Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from DMI Ex. 342. Thus, the total pick-up of Ex. 285 over DMI Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Ex. 15).

48. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire

has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

49. I note that Arthrex does not address the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, Arthrex only asserts that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as Arthrex defined the novel and basic characteristics. Rather, the relevant issue as Arthrex framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

50. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Arthrex, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Arthrex.

51. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties

attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 2 at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (*id*. at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

52. I disagree with Arthrex that FiberWire's coating has a "material" effect because Arthrex basically *excludes* coated sutures from the 446 Patent claims. But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to ***further*** improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. ***Most preferably***, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating ***may be*** eliminated saving expense as well as avoiding the associated braid stiffening.

(*id*. at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

53. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Arthrex attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set

of continuous and discrete yarns (*id*. at 2:40-42). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (*id*. at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (*id*. at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. 8 at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. 2 at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. 20, 21, and 22. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as is shown by its product development (Ex. 3 at 68:25-70:13). The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. 2 at 2:58-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. 3 at 68:25-70:13). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. 2 at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "***further***" improve the handleability of the suture (Ex. 2 at 6:5-18) (emphasis added). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. 2 at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Exs. 20, 21 and 22). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

54. I further disagree with Arthrex's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. 2 at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (*id*. at 1:32-43), a PTFE coating (*id*. at 1:43-54), a monofilament like surface on a multifilament braid (*id*. at 1:55-2:2), and an elongated core (*id*. at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (*id*. at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

55. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (*id*. at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (*id*. at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

3. Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material

56. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. 23 at 87:7-13; 88:1-3; 96:18-19; 98:18-21). He also stated that he could not "clearly feel a difference" (*id*. at 88:9-10). This supports my opinion that any purported differences are not material.

57. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (*id*. at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (*id*. at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (*id*. at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in surgery (*id*. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

58. I note that Arthrex criticizes for me for not remembering at my deposition that I had considered certain information in my analyses that Dr. Mukherjee had considered. But after reading Arthrex's criticism, I consulted my Rebuttal Expert Report and it refreshed my memory that I had considered those materials. As I explained in ¶54 of my rebuttal report, I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products with different coatings, different applications of coatings, and different suture constructions. Although I did not recall at my deposition that I had reviewed these documents, I do now recall reviewing them to determine

whether they discussed FiberWire's coating, and they do not. I have provided three reports in this case and reviewed thousands of pages of documents. My deposition was on July 26-27, 2006, just over three months since I finalized my rebuttal report. Although I did not recall that one paragraph from my three reports at my deposition, Arthrex's counsel did not ask me to review that paragraph when asking questions about these documents. If he had, it would have refreshed my memory on the issue.

V. Under Mitek's Definition of the Novel And Basic Characteristics, FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

59. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

60. I understand that Mitek has asserted that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the

second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (Ex. 26 at ARM001976).

61. The ‘446 Patent specifically contemplates, in the “Detailed Description of the Invention,” that the braided sutures of the invention can be coated (Ex. 2 at 6:5-21). The ‘446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (*id*. at 6:9-11). Thus, the ‘446 Patent’s description of the invention as contemplating coatings supports my opinion that FiberWire™’s and TigerWire™’s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the ‘446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.[4]

62. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Ex. 21 (DMI Ex. 284), Ex. 22(DMI Ex. 342), Ex. 23 (DMI Ex. 285).

63. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

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[4] My opinion is further supported because the ‘446 Patent claims a “suture.” I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

64. It is my expert opinion and observation that the coating only appears on the surface of the braid.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: September 1, 2006 /s/

BROOKSTEIN DECLARATION EXHIBIT 1

David Brookstein, Sc.D.
Dean and Professor of Engineering
Philadelphia University
Philadelphia, PA 19144
(215) 951-2751

Curriculum Vitae

Education:

- Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.
- Bachelor of Textile Engineering, Georgia Tech, 1971.
- Harvard University School of Business Summer Program on Research Management, 1990.
- Harvard University Graduate School of Education MLE Summer Program, 1998

Professional Experience:

Philadelphia University

1994 - Present Dean and Professor of Engineering
School of Textiles and Materials Technology (soon to be the School of Engineering and Textiles)

Chief academic and financial officer for a school with undergraduate majors in industrial and systems engineering. textile engineering (ABET accredited), textile technology, textile design, fashion design and fashion industry management. Master of Science programs are offered in textile engineering, textile design, textile marketing, global textile marketing, on-line MBA in textile and apparel marketing and fashion-apparel studies. Developed first Philadelphia University program, - Ph.D. in textile engineering and science. Principal Investigator for largest outside funded research grant received by Philadelphia University, $2.7 million DoD grant for the Laboratory for Engineered Human Protection. Philadelphia University Program Leader for the National Textile Research Center, a $10 million/annum grant for a consortium of universities that include Auburn Unviersity, Georgia Tech, North Carolina State University, Clemson University, UMASS-Dartmouth, Cornell University and University of California-Davis. Led the development of the Philadelphia University Research Center in the Manayunk section of Philadelphia.

Harvard University

2002 – 2003 Visiting Scholar
Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences)

Albany International Research Co. - Mansfield, MA

1992 - 1994 Associate Director
1983 - 1992 Assistant Director
1980 - 1982 Senior Research Associate

Directed all activities of the professional engineering group responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. Accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous preforms for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures. Engineering innovations led to 11 US patents and many other inventions protected by trade secret. Member of the senior management staff of the organization.

Northeastern University - Boston, MA

1981-1983 Adjunct Professor in Mechanical Engineering

Taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

Georgia Institute of Technology, College of Engineering

1975 - 1980 Assistant Professor of Textile Engineering

Taught and conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems. Obtained substantial funding from US DOE and US DOD. Active participant in College of Engineering co-op undergraduate programs.

Outside Professional Activities:

•Advisory Board of the College of Engineering, Georgia Tech.
•Member of the University City Science Center Research Provost Roundtable
•Adjunct Full Professor, North Carolina State University
•President, The Fiber Society (1996)
•Chairman, Textile Engineering Division-American Society of Mechanical Engineers (1994-1996)
•Research Associate - Textile Research Institute/Princeton
•Member of the Manufacturing Technology Operating Group of the ASME
•Peer Reviewer for ASME Fellows

Memberships:

- American Society for Engineering Education
- Council of Engineering Deans
- Institute of Industrial Engineers
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- American Conference of Academic Deans
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994,
- President (1996)
- SAMPE - Society for Advanced Materials and Process Engineering
- The Textile Institute

Awards and Honors:

- ASME – Fellow, 1995
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994, President, 1996
- The Textile Institute (United Kingdom) – Fellow, 1992
- Georgia Tech Academy of Distinguished Engineering Alumni, 1999
- Techtextil Innovation Prize, 1993 (Germany)
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2. U.S. Patent 4,497,866 "Sucker Rod," An elliptical cross-section braided cdmposite rod for pumping oil.
3. U.S. Patent 4,602,892 "Sucker Rod," A braided composite rod and coupling for pumping oil.
4. U.S. Patent 4,841,613 "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.
5. U.S. Patent 4,909,127 "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.
6. U.S. Patent 5,004,474 "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.
7. U.S. Patent 5,357,839 "Solid Braid Structure" A 3-D system for producing braids.
8. U.S. Patent 5,358,758 "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.
9. U.S. Patent 5,411,463 "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.
10. U.S. Patent 5,501,133 "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.
11. U.S. Patent 5,697,969 "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

Non-patentable trade secret inventions developed at Albany International Research Co.

1. Fiber-reinforced composite rocket igniter for Small ICBM and Pegasus Air-Launched Vehicle
2. Specialty vascular grafts and bio-absorbable orthopedic implants
3. Flexible air-beam for military structures
4. New method for drying paper during the papermaking process
5. Complex, reduced delamination rocket motor exit cones

BROOKSTEIN DECLARATION
EXHIBIT 2

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] D04C 1/00

[52] U.S. Cl. 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search 606/228, 230, 231; 87/7, 8, 9; 428/225

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Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

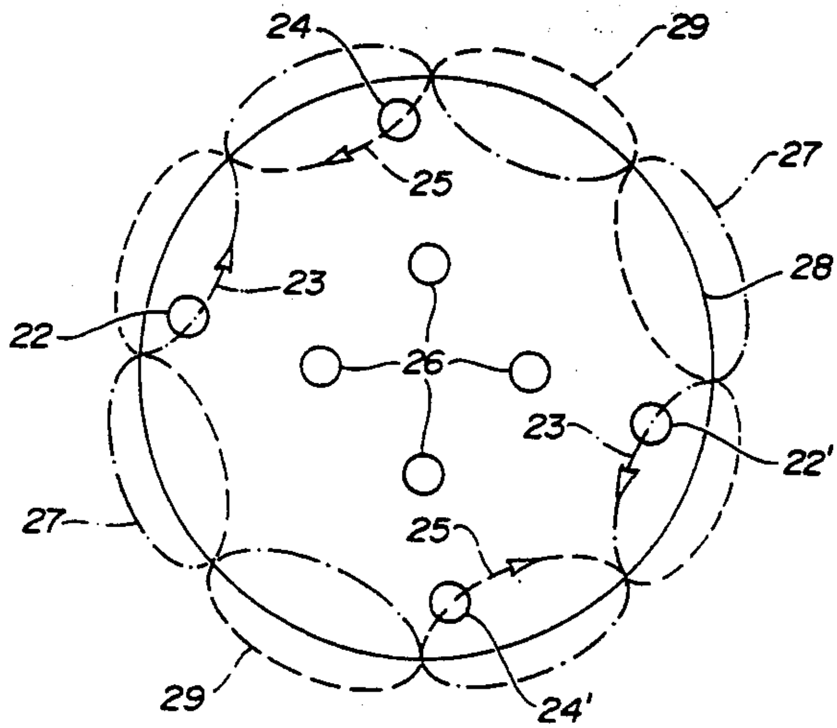


FIG-2

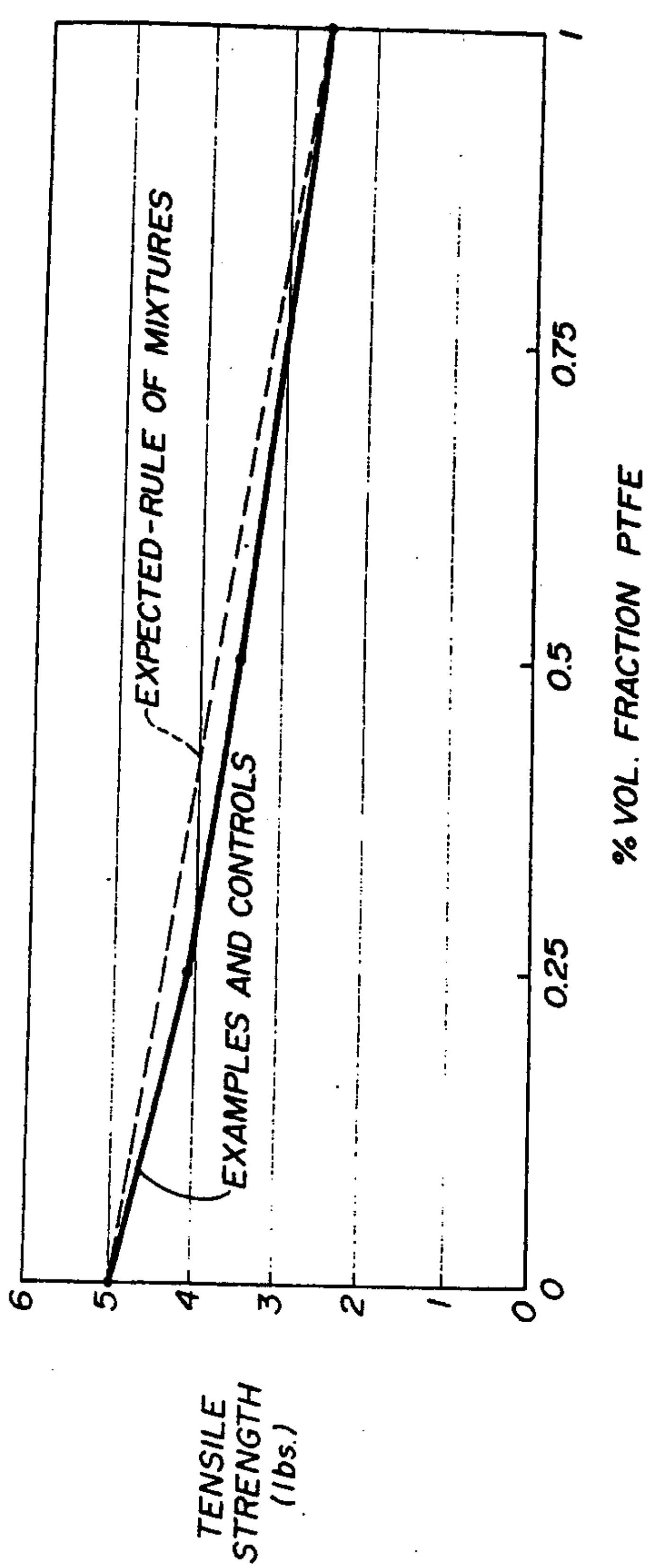
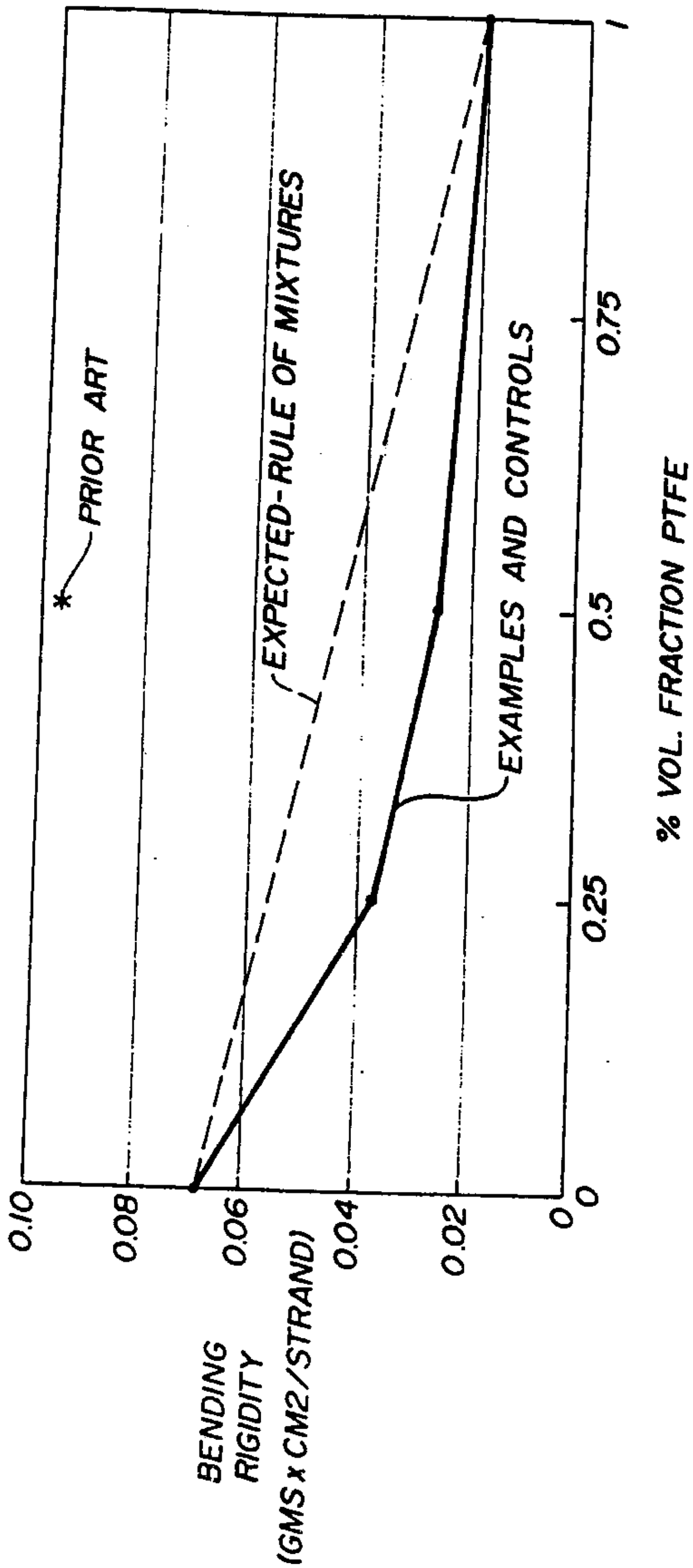

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
BENDING RIGIDITY (GMS x CM2/STRAND)
0.10
0.08
0.06
0.04
0.02
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

BROOKSTEIN DECLARATION
EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

Arthrex, Inc., a Delaware
Corporation,

Defendant.

CIVIL ACTION
NO. 04-12457 PBS

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

Q. And you don't recall whether or not the polyester suture from Arthrex had a core?
A. You said from Arthrex. You're talking about Pearsalls now?
Q. I'm sorry. The 100 percent polyester suture from Pearsalls, did it have a core?
A. Don't know.
Q. Don't know? And the polyester that was braided in the polyester suture from Pearsalls, do you know what type of polyester that was?
A. No.
Q. When's the first time that you went over to England to visit Pearsalls?
A. Don't remember.
Q. How many times have you been over to England to visit Pearsalls?
A. Three to five.
Q. When you were involved in the process of selecting this polyester suture from Pearsalls, did you go over and visit Pearsalls?
A. No.
Q. No? At some point, Arthrex -- Let me back up.
What was the next suture that you can remember Arthrex selling after the polyester?
A. Jenzyme Tevdek.

Q. Were you involved in the selection of the Tevdek suture?
A. What do you mean involved? Primary identification or selection or did I know the company? Or you are going to have to -- When you say involved, sir, I need to know exactly what you're talking about.
Q. Okay. Were you involved in the selection of this Tevdek suture from Jenzyme?
MR. SOFFEN: Objection; vague. He just said he doesn't have --
A. I'm not sure -- Again, when you say involved, I'm involved in this, but I'm not asking the questions. So you need to -- when you say involved, what does involved mean exactly? I -- I was the engineer that was responsible for saying yes, this is a product that meets engineering specifications.
Q. Okay. Did you recommend that Arthrex sell the Tevdek sutures?
A. From an engineering standpoint, the material met the specification or engineering requirements to be used with a suture anchor.
Q. And what were the engineering requirements that you reviewed Tevdek suture for?
A. Knot strength, tensile strength, color, biocompatibility. You know. It's -- on and on.

Q. Knot tiedown? Is that one of the considerations?
A. Knot -- knot strength.
Q. Was knot tiedown one of the considerations that --
A. Well, obviously, if you are going to tie a knot, I mean, it's going to be tied down to something. Yes. The makeup of the suture anchor, so, yes.
Q. So the answer is yes?
A. Yes.
Q. Okay. When you were selecting the Pearsalls suture, was knot strength a consideration?
A. Of course.
Q. And when you were selecting the Pearsalls suture, was tensile strength a consideration?
A. Yes.
Q. When you were selecting the Pearsalls suture, was knot tiedown a consideration?
A. Knot tiedown, knot strength are -- in my thinking are similar or the same thing.
Q. Same thing?
A. (Witness nods head affirmatively).
Q. What do you mean -- In your thinking, when you say knot strength, what do you mean?
A. Surgeon's application is to tie a knot. That is affixing it to -- in approximation to tissue to bone.

That is knot tiedown. And there's a knot placed in the suture, so -- so tying a knot and knot tiedown are the same things as far as I'm concerned.
Q. Okay. You just said tying a knot and knot tiedown is the same thing. My question was slightly different. Knot strength versus -- What is your understanding of knot strength?
A. It's the mechanical tensile of the suture's ability to -- to, after tying a knot, before breakage.
Q. Did you generally consider knot strength to be determined by tying a knot in a suture and testing it on a tensile --
A. Yes.
Q. -- testing machine?
A. Yes.
Q. How about knot tiedown? Is that --
A. We didn't test for knot tiedown.
Q. So you -- Before, you said knot strength and knot tiedown were the same thing.
A. That's why I said that we tested for knot strength -- okay -- for -- of tying a knot. And I consider those the same things. So we didn't -- we didn't test specifically for tying soft tissue down. We tested the knot as tying a knot versus -- what the standard calls for and doing a pull test on it.

Q. Let me back up to make sure this is clear. Knot strength versus knot tiedown. In your mind, are they the same thing or are they different?
A. I'm not sure I understand your question. Say that again.
Q. Sure. Knot strength --
A. Mmm-hmm (affirmative).
Q. -- which I think you testified that you understood to be tying a knot in a suture and pulling it on a tensile machine -- tensile tester machine to determine the strength at which the knot will break; right?
A. Yes.
Q. Okay. Then there's another term called knot tiedown, and I'm trying to understand whether, in your mind, you think that's the same as knot strength or do you use that term to mean something else?
A. They're closely related.
Q. And how are they related?
A. When you have a knot tiedown, you've tied a knot. The strength of the knot is going to affect the ability to hold -- to approximate the tissue in the tiedown area that you're talking about.
Q. If the knot had a good tiedown or a bad tiedown, what do you mean by that?

A. Its ability to approximate the tissue and hold it in place through biomechanical forces.
Q. So that's related to knot strength, but it's not necessarily the same thing; is that the way you're using the term?
A. Yes.
Q. The way I heard you describe knot tiedown was you said the ability to approximate the tissue and hold it into place through biomechanical forces.
A. (Witness nods head affirmatively).
Q. When you say ability to approximate the tissue, what do you mean by that?
A. Shift tissue in the position that the surgeon would like for it to be on the bone.
Q. Shift tissue; did you say?
A. Yes.
Q. S-H-I-F-T?
A. Yes.
Q. So the knot's moving the tissue?
A. The suture is holding -- the suture loop with the knot in it, is holding the tissue in the position that the surgeon would like for it to be on bone.
Q. That's taking the place of the tissue? When you say approximate the tissue, how is it approximating tissue?

A. It's -- The tissue is here. The location the surgeon wants it here. The suture loop as it is tied moves the tissue into position.
Q. Holds it there?
A. Yes.
Q. And what -- what biomechanical forces were you referring to?
A. Forces on the glenohumeral joint.
Q. In a knot strength test, it's the forces are being applied and generally in one direction; correct?
A. Yes.
Q. The biomechanical force that you are referring to in this knot tiedown, the forces are coming from different directions; right?
A. Yes.
Q. Okay. When you are referring to knot tiedown then, you're referring to -- you're referring to it in a sense as a strength?
A. Are you finished? Is that the question?
Q. Right.
A. I don't believe -- Say it again then.
Q. Sure. Knot tiedown, the way you're referring to it, it's a strength then? It's kind of like -- because knot strength would be measured in p.s.i.
A. I said that's one of the attributes of it.

That's not the total attribute of it. I mean it's to approximate tissue into position is knot tiedown.
Q. Well, what else would be included?
A. I just told you. Approximate tissue, strength.
Q. So the strength would -- I understand the --
A. The size of the knot bundle. You know, there's --
Q. Size of the knot bundle?
A. Yes.
Q. What do you mean by that?
A. How large the knot is once it has been tied and cut.
Q. So knot tiedown includes the size of the knot bundle?
A. Yes. You know, the knot tiedown -- I want to say this -- that's not a term that we specifically use, so it's a little bit foreign. I mean I don't -- I've never had a surgeon ask me about knot tiedown.
Q. Okay.
A. So I didn't -- your -- I'm not sure where you're going with this, but there's -- we did knot testing and we did straight pull testing of the suture so that your knot tiedown, I'm -- I'm not real sure what you're asking for there. I --
Q. Well --

42

A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they

43

compared to the competitive products.
Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength

44

and tensile strength; right?
A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr.

45

Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."
And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

46

A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

47

Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is

48

processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had

49

this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes.
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent, I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

54

MR. SOFFEN: Objection; asked and answered. You've asked him the same thing multiple times. But you can answer.
A. I've lost count, it's been so many times, but the answer again is yes.
Q. Okay. And Dr. Burkhart said that was a killer idea?
A. What was a killer idea?
Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question.
Did Dr. Burkhart say that your idea to braid PET with the ultra-high molecular weight polyethylene to improve knot security was a killer idea?
A. Yes.
Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra-high molecular weight polyethylene braided?
A. Yes.
Q. And you tested that prototype?
A. Yes.
Q. And you said that that prototype had good knot strength?
A. Correct.
Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

55

A. Yes.
Q. And the prototype of PET and ultra-high molecular weight polyethylene braided together also had good tensile strength?
A. Yes.
Q. And after you tested this second prototype, if you will, of the PET braided with ultra-high molecular weight polyethylene, was then the decision made to pursue trying to commercially develop this idea?
A. Yes.
Q. Did you -- when you made -- Who made the decision to go forward and try to commercialize this idea?
A. Myself and Reinhold, surgeons that we collaborated with, marketing people. You know, it wasn't just myself.
Q. Okay. Was this prototype that had the PET braided with the ultra-high molecular weight polyethylene, was it -- did it have a coating on it?
A. Yes.
Q. It did?
A. (Witness nods head affirmatively).
Q. And what was the coating?
A. I forget the name. It's like an MED2174s.
Q. That was on the prototype?
A. Which prototype are you referring to now?

56

Q. I'm talking about the --
A. The second prototype with the PET?
Q. Correct.
A. Yes.
Q. The second prototype that had the coating on it?
A. Yes.
Q. And was that part of your initial idea, or was that -- because I thought you said your initial idea was to add the PET. Was it also to coat it, or was that something that came later?
A. If you're going to market the product, it needs the coating on it, sir.
Q. Okay. But the prototype that was manufactured that you asked --
A. Most likely, it was coated, because it needed to be as the final product would be marketed.
Q. You said most likely. Do you remember or you don't remember whether the prototype that had the PET and the ultra-high molecular weight polyethylene was coated?
A. I can't tell you for sure that it was at that prototype stage.
Q. Okay. Was this prototype that you had -- after you tested the prototype with PET with ultra-high --
A. Excuse me. I want to change that.
Q. Okay.

57

A. I never got samples of constructions from Pearsalls without a coating unless I specifically asked for it not to be coated. So there's a very high probability that the suture came as -- the second prototype -- as coated.
Q. That was standard for them to coat it, in other words?
A. Yes.
Q. Okay. So the initial prototype that was ultra-high molecular weight polyethylene, did you ask for that not to be coated?
A. No.
Q. So chances are that that one was coated?
A. Quite possibly.
Q. After you tested the prototype of PET and ultra-high molecular weight polyethylene braided together, did you believe that it would then work as a suture?
A. Yes.
Q. Okay. Is there anything else you think you needed to do in order to determine whether it would work as a suture?
A. Yes.
Q. What did you need to do?
A. Biocompatibility toxicity testing, bioburden levels, all the design control GNP items that need to be

decitex?
A. No. No, I can't remember that.
Q. Do you recall evaluating any samples that had Dyneema 400 denier or higher?
A. No.
Q. Do you think you did or you just don't recall?
A. I received -- I'm sure I received the samples. What I did with them, I don't recall.
Q. Okay. How long -- how much before this letter do you think you came up with the idea to use the ultra-high molecular weight polyethylene with PET blended together?
A. Whatever the Chicago National Sales Meeting was. The flight just before the start date would be the time that I came up with the idea. I don't know what that time is. I just remember the circumstance.
Q. You say Chicago National Sales Meeting?
A. That's correct.
Q. Is that Arthrex National Sales Meeting?
A. Yes.
Q. Was that a meeting with all the Arthrex sales reps.?
A. That's correct.
Q. And it was sometime before the July -- It was the meeting before the July 10, 19 -- I'm sorry. The meeting where you came up with the idea was the meeting before the

July 10th, 1998 date on this letter?
A. Yes.
Q. I show you DePuy Mitek Exhibit 324. Do you recognize Exhibit 324 as a letter from you to Mr. Hallett?
A. I don't recall the letter, but I recognize my name and the contact person. But the specific circumstances of the letter, I don't remember.
Q. Based on your prior testimony, is it then true that this letter was after you came up with the idea and after you evaluated the prototype?
A. Yes. After I came up with the idea, yes.
Q. Okay. Was this letter sent before or after you came up with the -- I'm sorry. Was this November 16th, 1998 letter sent before or after you came up with the -- Sorry. I will rephrase the question.
Was the November 16th, 1998 letter, Exhibit 324, sent before or after you evaluated the prototype of ultra-high molecular weight polyethylene braided with PET?
A. I don't recall.
Q. When you had the prototype of PET and ultra-high molecular weight polyethylene made, do you know if Pearsalls specifically made that or if they just pulled it off their line from something else?
A. I'm sure they made it.
Q. They specifically made it?

A. Yes.
Q. It's not like they had a product that they could just give to you?
A. No.
Q. In your letter, you say you tested the samples of Dyneema. Do you see that?
A. Yes.
Q. And then you say, "Can you build a 25 percent Dyneema/75 percent polyester blend in Size 2 that is very flexible (like the existing suture or the Ethicon sample) and send it to me to test"; do you see that?
A. Yes.
Q. Does that Ethicon sample, does that refer to an Ethibond?
A. Yes.
Q. And you say, "If we get the" -- "If we can get this blend correct, we will have a terrific advancement in suture for our soft tissue anchors"; do you see that?
A. Yes.
Q. What did you mean by that?
MR. SOFFEN: Objection; vague. It states what it states. What's the question?
Q. Do you understand the question?
A. I'm not sure what -- what you're asking.
Q. I would like to know what you mean by in your

letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement."
What did you mean by "If we can get this blend correct"?
A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
Q. Wait a second. You said optimization of two materials.
A. (Witness nods head affirmatively).
Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
A. During -- during the -- during that period of time, yes.
Q. So you were balancing off the properties of each material to try to get the optimum properties --
A. Tensile strength.
Q. To get the optimum tensile strength?

70

A. (Witness nods head affirmatively).
Q. What about knot security?
A. Yes.
Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
A. Yes.
Q. Were the product samples that were being made at this time in November of 1998, around this time, were they being made on a carrier braid machine?
A. Yes.
Q. I show you DePuy Mitek Exhibit 325. It's a letter dated November 16th, 1998 from Mr. Hallett to you. Do you see that?
A. Yes.
Q. Do you recall receiving this letter?
A. No.
Q. It says -- Mr. Hallett says in the letter, "Please find enclosed a matrix of information of the

71

samples that you took with you on your visit to Pearsalls. I will endeavor to proceed with the existing trial to match the US2 Excel Braid made by Ethicon, in polyester construction." Do you see that?
A. Yes.
Q. Did you pick up the samples from Pearsalls that are mentioned in this --
A. I don't recall.
Q. Do you recall whether they were actually -- Do you recall going over to Pearsalls and having them actually make samples while you were there?
A. Yes.
Q. And were these samples -- These aren't samples they pulled off the line? These are samples where they took yarns and braided them according to what you guys were considering?
A. Repeat the question again.
Q. Sure. I'm just trying to get the sense of whether the samples that you picked up while you were at Pearsalls that you saw being made, were they -- was it an existing product they were picking up off the product line, or was this -- you know -- yarns that were selected and braided and going through the manufacturing process that you particularly picked out?
A. The latter.

72

Q. Do you see under the yarns the first one is Dyneema?
A. Yes.
Q. And is has a DT number. Do you see that?
A. DT.
Q. Dt-no. Does that stand for DT number?
A. Where -- where do you see DT?
Q. The second column.
A. At the top as the heading, yes.
Q. Okay. Are you familiar that Pearsalls uses the terminology DT number for samples?
A. I don't recall what they use.
Q. You don't recall? Okay.
Was it the first sample -- Do you see where the first one is Dyneema and the second ones are Polys, the second through fourth are Poly/Dyneema? Do you see that?
A. Yes.
Q. Was the first sample of yarn here all Dyneema?
A. Evidently.
Q. Do you see in the second through the fourth yarns were a braided blend of Polyethylene and Dyneema?
A. Yes.
Q. Do you see the straight pull column?
A. Yes.
Q. I'm sorry. I may have misspoke.

73

The second through fourth yarns that are listed, the Poly/Dyneema, is that -- are they Polyester and Dyneema?
A. Yes.
Q. Not polyethylene and Dyneema?
A. It's ultra-high molecular weight polyethylene and PET.
Q. Okay. Do you see the column straight pull?
A. Yes.
Q. Do you know what that means?
A. Testing that they did in their lab with their tensile test machine in kilograms.
Q. Is that with a knot or without a knot?
A. That's without a knot.
Q. Okay. And do you see how the Dyneema one was 23.12 kilograms?
A. Yes.
Q. And Poly/Dyneemas were on the order of 34 to 36 kilograms?
A. Yes.
Q. Do you know why the difference in strength between the Dyneema one and the other ones?
A. You can't tell by looking at this report why there's a difference.
Q. And you don't remember?

78

Q. Okay. I show you DePuy Mitek Exhibit 164. Do you recognize Exhibit 164 as a letter from Mr. Hallett to you?
A. Yes.
Q. And did you receive Exhibit 164 on October 19th, 2000?
A. Evidently so.
Q. It says the subject is Polyester-Dyneema Braid. Do you see that?
A. Yes.
Q. And then it says, "Dear Don: Please find enclosed four DT trials samples for your inspection. These have been made using Polyester/Dyneema mixed either in the core -- I'm sorry -- mixed either in the cover or straight core to match US2. I have set up below a matrix of how each was made and the results for your information." Do you see that?
A. Yes.
Q. And the first sample is the DT PA23 sample. Do you see that?
A. Yes.
Q. And if you go down to the cover, it was 16 carriers in use each with one end of 138 d'tex Polyester per carrier. Do you see that?
A. Mmm-hmm (affirmative).

79

Q. So the first sample of DT PA23 had a cover that was all polyester; right?
A. Yes.
Q. And is this letter part of the development of FiberWire? It was sent to you in connection with the development of FiberWire?
A. Yes.
Q. If you turn over to the next page, the second sample is DT PA25. And if you look at the cover construction, it was 16 carriers in use, 8 carriers with one end of 113 polyester, 8 carriers with one end of 110 Dyneema. Do you see that?
A. Yes.
Q. So the PA25 had a cover that was a Polyester/Dyneema blend?
A. Correct.
Q. The DT PA26, the construction of that cover was 16 carriers in use, 8 carriers with one end of 113 polyester, 8 carriers with one end of 110 Dyneema. Do you see that?
A. Yes.
Q. So the DT PA26 had a Polyester/Dyneema braid construction in the cover?
A. Correct.
Q. And the DT PA27 had a cover of 16 carriers in use, 16 carriers with one end of 113 polyester per carrier. Do you see that?
A. Yes.
Q. So the DT PA27 had a polyester braided cover; right?
A. Yes.
Q. Okay. Now if you look at the knot pull strength of each, of the DT PA23, which was a polyester cover, had a 10.35 at the finish stage of knot pull?
A. Yes.
Q. And the DT PA25 had a knot pull at the center stage of 11.95?
A. Yes.
Q. Do you know what the finish stage is?
A. Yes.
Q. What is the finish stage?
A. After coating.
Q. Okay. And the DT PA26 had a knot pull of 12.87; do you see that?
A. Yes.
Q. And the DT PA27 had a knot pull at finish of 8.04. Do you see that?
A. Yes.
Q. So if you look back and look at the numbers, the first one, the DT PA23 was the polyester cover braid, and

80

81

its knot strength at finish was less than the DT PA25 and DT PA26; correct?
A. Yes.
Q. And DT PA27 was also a polyester cover, and its knot strength at finish stage was less than that of DT PA25 and 26; right?
A. Yes.
Q. Do you know why the DT PA23 and PA 27 samples had lower knot pull strength at the finish stage than DT PA25 and DT PA26?
A. Because there was no Dyneema in the jacket or cover.
Q. And you say that the finish stage was after coating, so all these products had the -- I'm sorry -- so you said the finish stage was after coating, so the DT PA23, 25, 26, and 27 all had coating on it?
A. Yes.
Q. They had the same coating?
A. Yes.
Q. They went through the same coating processes?
A. Yes.
Q. If you look at the d'tex of the Dyneema yarn that was used in these prototypes, it was -- in the cover, the DT PA25 had 110 Dyneema, and the DT PA26 also had 110 Dyneema in the cover? Do you see that?

102

Q. You're sure you did?
A. Yes.
Q. And what did you review it for?
A. Accuracy, to be sure it covered as much of a claim area as possible.
Q. Okay. Do you recall having any discussions with an attorney that this patent -- patent Exhibit 423 was not accurate?
A. I don't recall that, no.
Q. Do you recall asking an attorney to change anything in Exhibit 423 and having them say no?
A. I don't know. I don't recall.
Q. And do you see how on the front of Exhibit 423, if you look on the first page, it says the Agent, Attorney or Firm, do you see where it says Dickstein, Shapiro, Morin & Oshinsky, LLP; do you see that?
A. Yes.
Q. Do you recall working with attorneys from Dickstein, Shapiro, Morin & Oshinsky in preparing this application?
A. Yes.
Q. Do you recall working with Mr. Soffen in preparing this patent application that became the '423 patent?
A. Yes.

103

Q. Is Mr. Soffen generally the person you've worked with in preparing patent -- patent applications?
A. He's one of them, yes.
Q. Okay. And how about Mr. McGee?
A. Yes.
Q. Okay. Do you have an understanding that in providing a description of your invention, that the invention should be sufficiently described so that someone skilled in the art could make it?
A. Yes.
Q. Okay. If I could turn to paragraph -- the text beginning on Page ARM 286, the second paragraph, the description of the related art. Do you see that?
A. Yes.
Q. It says, "Suture strength is an important consideration in surgical suture material." Do you agree with that?
A. Yes.
Q. It says, "One of the strongest materials currently formed into elongated strands is an ultra-high molecular long chain weight polyethylene typically used for fishing lines and the like which is sold under the trade names Dyneema or Spectra." Do you agree with that?
A. Yes.
Q. It says, "However, this material, while much

104

stronger than ordinary surgical suture, does not have acceptable knot tiedown characteristics for use in surgical applications." Do you see that?
A. Yes.
Q. Do you agree with that?
A. Yes.
Q. Do you see the reference to knot tiedown?
A. Yes.
Q. Is that reference to knot tiedown what we referred to this morning as knot tiedown as you described it?
A. It's one of the items we referred to, yes.
Q. And how you defined it this morning, is -- are you using that same definition here?
A. Yes.
Q. Okay. If you go on the front page of this document, it notes Patent Documents -- U.S. Patent Documents References Cited; do you see that?
A. Yes.
Q. And there's a section of Foreign Patent Documents and Other Publications. Do you see that?
A. Mmm-hmm (affirmative). Yes.
Q. Do you recall whether you asked for any fishing line products to be disclosed to the patent office that used ultra-high molecular weight polyethylene?

105

A. Don't recall.
Q. Go to the Detailed Description of the Preferred Embodiments. Do you see that? It begins on Column 2.
A. Yes.
Q. It says, "Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown."
A. Excuse me. I'd like to interrupt you --
Q. Sure.
A. -- on one of your comments. I want to be sure I get that correct. The -- When you said whether I specifically asked for a fishing line or fishing line patents to be looked at --
Q. I didn't say patent. I said products.
A. Products? The key word would have been put in for the materials used, and if those then had a hit, if you will, with the fishing line, then that patent would have come up.
Q. Right. But I'm just talking about products like -- that were on the market like fishing line products.
A. No. No. That was --
Q. Like the one Pearsalls made.
A. No, we didn't look at Spider Wire or other fishing lines.

BROOKSTEIN DECLARATION
EXHIBIT 4

US006716234B2

(12) **United States Patent**
Grafton et al.

(10) **Patent No.:** **US 6,716,234 B2**
(45) **Date of Patent:** **Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

(75) Inventors: **R. Donald Grafton**, Naples, FL (US); **D. Lawson Lyon**, Exeter (GB); **Brian Hallet**, Taunton (GB)

(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **09/950,598**

(22) Filed: **Sep. 13, 2001**

(65) **Prior Publication Data**

US 2003/0050666 A1 Mar. 13, 2003

(51) **Int. Cl.**⁷ **A61L 17/04**
(52) **U.S. Cl.** **606/228**
(58) **Field of Search** 606/228

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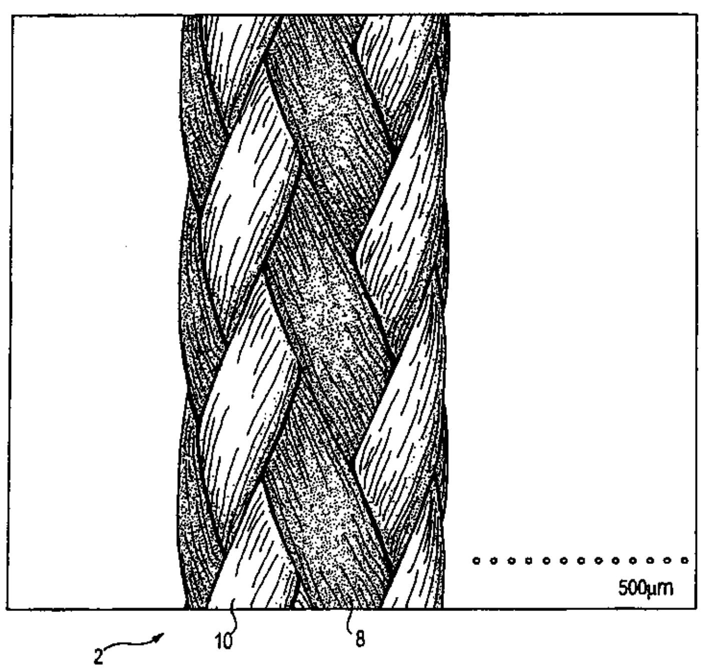
Primary Examiner—David O. Reip
(74) *Attorney, Agent, or Firm*—Dickstein Shapiro Morin & Oshinsky, LLP

(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets



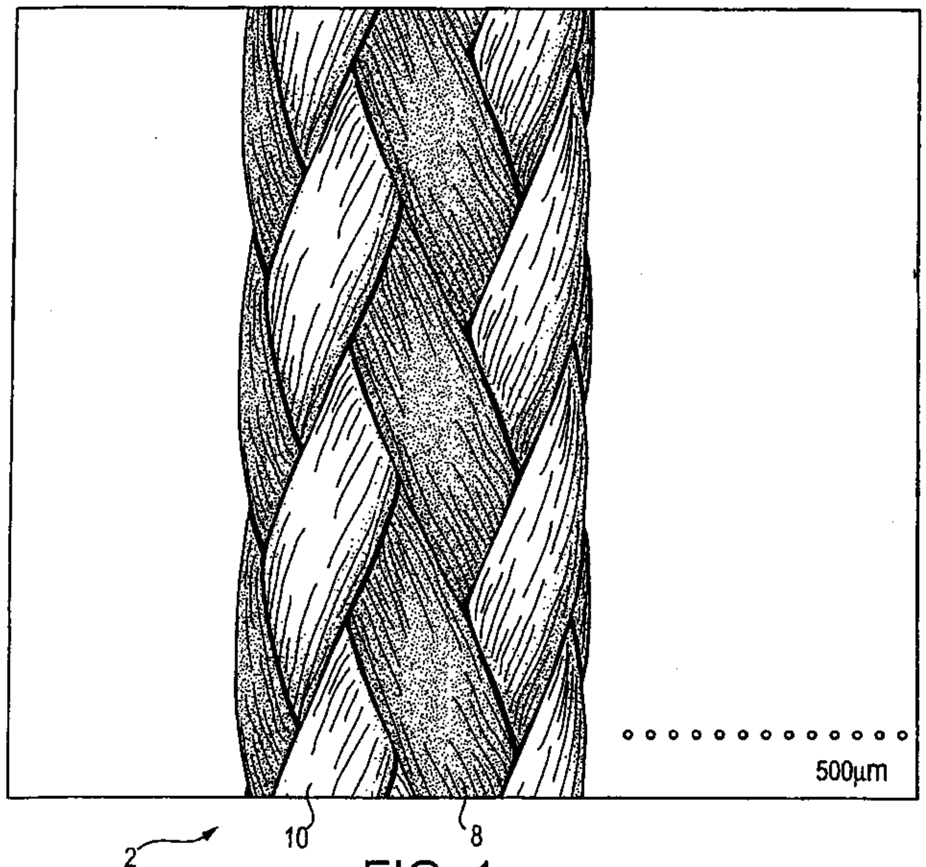


FIG. 1

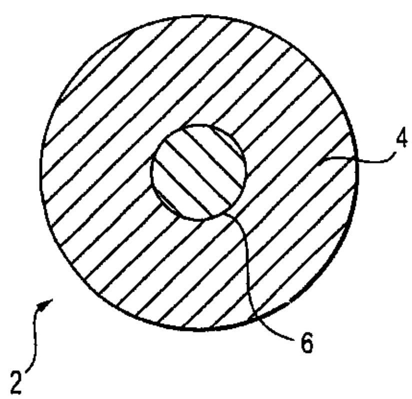


FIG. 2

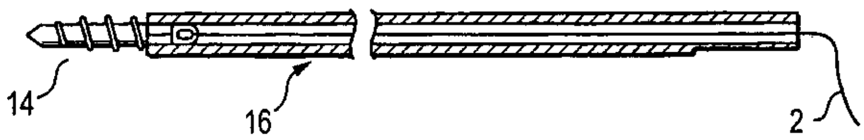


FIG. 3

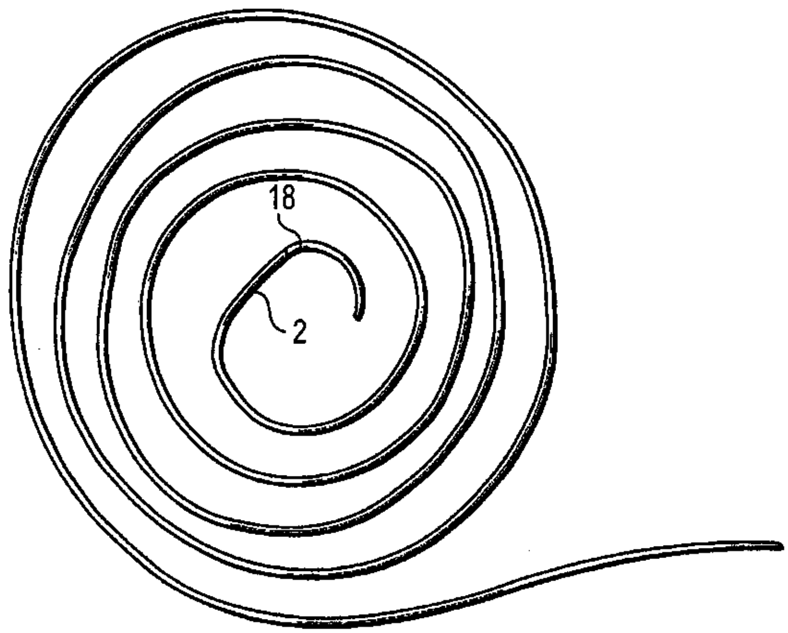


FIG. 4A

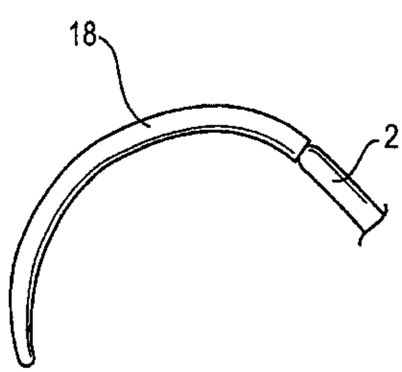


FIG. 4B

HIGH STRENGTH SUTURE MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. 1 is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. 2 is a schematic cross section of a length of suture according to the present invention.

FIG. 3 is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. 4A and 4B show the suture of the present invention attached to a half round, tapered needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown. Suture 2 is made up of a cover 4 and a core 6 surrounded by the cover. See FIG. 2. Strands of ultrahigh molecular weight polyethylene (UHMWPE) 8, sold under the tradename Dyneema or Spectra, and strands of polyester 10 are braided together to form the cover 4. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture 2 is attached to a suture anchor 14 as shown in FIG. 3 (prepackaged sterile with an inserter 16), or is attached to a half round, tapered needle 18 as shown in FIGS. 4A and 4B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim 1, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim 1, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim 1, wherein the core comprises a bout 30% of the filament.

5. The suture filament of claim 1, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim 1, further comprising a coating disposed on the cover.

7. The suture filament of claim 1, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

BROOKSTEIN DECLARATION
EXHIBIT 5

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

HIGHLY CONFIDENTIAL

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
11th January 2006

MR. BONELLA: What do you mean by that?
MR. TAMBURO: -- but I take you at your word that this is the 30(b)(6) portion of the deposition, and again, to the extent that this testimony you are requesting right now is duplicative of testimony that was already given by Pearsalls in the past for this topic, topics number 4, 5, 6 and 7 of the original notice, Arthrex and Pearsalls are objecting to the duplicative testimony requested.
MR. BONELLA: Let's just move on. We will resolve it later. Exhibit 280. Do you recognize that, Mr. Hallett?
A I recognize it as it is.
Q What is Exhibit 280?
A It is a result of a batch of US2 FiberWire.
Q Exhibit 280 is batch testing results?
A Hmm hmm.
Q The tests describe in Exhibit 280 are, those tests that are run in the standard, ordinary business of Pearsalls?
A Correct.
Q Do you see the test at the intermediate stage?

A Yes.
Q Can you label in the manufacturing flowchart where that test was done? Can you label that as the intermediate stage? Okay. So, where you have labeled Exhibit 280 interim/stage on Exhibit 279 reflects the intermediate stage testing done in Exhibit 280?
A Yes.
Q If you could identify -- there is a measure stage testing in Exhibit 280; correct?
A Hmm hmm.
Q Could you label on Exhibit 279 where the measure stage testing is?
A So, do you want me to put the --
Q If you could just put, "Measure stage"? "Exhibit 280 measure stage", and there is also the stretch stage. Would you label where that is in Exhibit 279? And there is also the dye stage testing. Could you label where that is in Exhibit 279? Exhibit -- you have labeled in Exhibit 279, "Exhibit 280 dye stage", and that refers to the dye stage testing in Exhibit 280?
A Yes.
Q The dye testing that is done in Exhibit 280, is that all -- is that of samples of FiberWire

that have undergone the dyeing and scouring processes and all processes before that?
A Yes.
Q You have labeled Exhibit 280, "Stretch stage"?
A Hmm hmm.
Q On Exhibit 279; correct?
A Yes.
Q The samples -- I am sorry, the stretch stage testing that is in Exhibit 280, does that undergo the stretching in all processes before that?
A Yes.
Q The samples that have gone -- that are stretch-tested in Exhibit 280 -- I am sorry, I will rephrase the question. The samples that have been stretch-tested as reflected in Exhibit 280 have not been coated. Is that correct?
A No.
Q "No", it is not correct?
A No. It is not correct.
Q The samples that have been stretch test -- I am sorry, the samples that are tested at the stretch stage have undergone the stretching and coating processes?
A Yes.

Q Are you sure about that?
A Repeat the question again.
Q Sure. The stretch testing, samples that are tested at the stretch stage as in Exhibit 280, have they undergone the stretching and coating processes that are reflected in Exhibit 279?
MR. TAMBURO: Asked and answered, objection.
MR. BONELLA: Mr. Tamburo is going to object to questions, but unless he instructs you not to answer you have to answer the question.
A Yes.
Q The intermediate stage testing, have those samples been stretched and coated?
A Yes.
Q What is the difference between the intermediate stage testing and the stretched stage testing samples?
A They are tested before they are actually coated.
Q Which are tested before they are coated?
A The yarn. The braid.
Q The samples that are tested during the stretched stage, have they been stretched?

82

process?
A It is not a stretch as such, it is just -- we call it stretching because it is run through some pads just to align all of the filaments in the yarn.
Q What do you mean by that?
A Well, it just pulls it straight.
Q Pulls it straight? The material isn't stretched?
A Very minute.
Q Very minute. And then the coating that we see here, it goes through a bath or a dip of glue seal and then the FiberWire is put through?
A It is a bath. We use it as a bath.
Q "Bath". Okay. And what is the rate at which the yarn passes through the bath?
A 20 metres per minute.
Q Is that the same for all FiberWire?
A Yes.
Q And then this machine here dries it?
A There are four (inaudible) which actually dry it as it is going through.
Q And then it is wound up to a bobbin at the other end?
A To that bobbin on the other end.
Q Now, as the FiberWire yarn itself goes

83

through the stretching and then the coating, does the process change in anything itself?
MR. TAMBURO: Object to the form of the question, calls for a legal conclusion.
A Do I have to answer that?
MR. TAMBURO: You can answer, yes.
A It actually makes it stronger in the lubrication of the actual suture when it is being used afterwards.
MR. BONELLA: The material that is braided, the yarn, both the PET and the polyester, does any material change happen to them?
MR. TAMBURO: Object to the form of that question.
MR. BONELLA: So, no material change happens to the polyester and ultra high molecular weight polythethylene as the FiberWire goes through the stretching and coating processes?
MR. TAMBURO: Same objection.
A No.
MR. BONELLA: To the wire?
A Can you repeat the question?
Q Sure. The FiberWire yarn for all sizes of

84

FiberWire undergoes this stretching process here; right?
A Correct.
Q Now, when the yarn comes in and goes through the stretching process, does any material change take place during the stretching process?
MR. TAMBURO: Same objection.
A No.
MR. BONELLA: Are there any changes in the strength characteristics of the yarn after the --
A Yes.
Q Let me rephrase the question. During the stretching process, is there any change to the stretch properties?
MR. TAMBURO: Same objection.
A Yes.
MR. BONELLA: In what way?
A It gets stronger.
Q The yarn is stronger after the stretching process?
A Yes.
Q When you say, "Stronger", what type of strength are you talking about?
A The long strength of it goes up.

85

Q The long strength of it goes up?
A Yes.
Q How about the tensile strength?
A Yes.
Q Any other strengths that go up or down before or after the stretching process?
MR. TAMBURO: Objection, outside the scope of this 30(b)(6) notice. The questions were asked and answered already previously in the United States during the previous 30(b)(6) deposition, so I object to this line of questioning.
A The extension goes down.
MR. BONELLA: The what does?
A The extension.
Q What do you mean by extension?
A It doesn't need so much -- more stretching in the braid.
Q No more stretching in the braid. Is that something that happens after?
A Yes.
Q What does that alter in the property?
A Extension.
Q Is that the same as elongation?
A Yes.

Q Does the modulus for the material change during the stretching process?
MR. TAMBURO: Same objection.
A I don't know.
MR. BONELLA: Is there testing done on that?
A No.
Q Do you know what I mean by, "Modulus"?
A Whether it alters.
Q Right.
A Yes.
Q Do you know what the modulus is referring to?
A I should imagine the make-up of the ultra high ...
Q The modulus I am referring to would be the slope of the stress strength, the stressed strain curve.
A The curve of the --
Q No. If you did a test, a stress strain plot for FiberWire before and after the stretching process, does the slope of that curve change at all with respect to the FiberWire?
MR. TAMBURO: Objection, calls for speculation, asked and answered.

A I don't know.
MR. BONELLA: You don't know whether it does?
A Correct.
Q Now, in the dyeing process, what pressure is that done at? I am sorry, the coating process. The coating process. What temperature is that done at?
A I am not. 27 degrees.
Q Celsius?
A Yes.
Q Pressure? What is the pressure? Atmospheric?
A I don't know.
Q There is no pressure put into this machine?
A No.
Q Is there a solvent used in this coating?
A Yes.
Q What is that?
A Xylene (Phonetic).
Q Any other material used in the coating process?
A No.
Q What is the purpose of the Xylene?

A It helps to penetrate the new seal coating within the braid structure. It dilutes the coating as well as attaching itself.
Q Where in the processing is the Xylene added to the machine?
A In the tank.
Q So, is the Zylene mixed together in the tank for the FiberWire to be put through it?
A That's correct.
Q Any material properties change to the FibreWire yarn itself during the stretching and the coating process?
MR. TAMBURO: Object to the form of the question. Calls for an expert conclusion, and outside of the scope of this 30(b)(6) notice.
A Change?
MR. BONELLA: Any material process altered by the ultra high molecular weight polythethylene or the polyester?
MR. TAMBURO: Object to the form of the question, calls for a legal conclusion and speculation and it has already been covered in a previous 30(b)(6) deposition.
A I don't know.
Q You don't know?

A No.
Q Why don't you know?
A I am not sure of the question you are asking.
Q For example, the ultra high -- the FiberWire braid that goes, that comes out of the stretch, then goes through the process, after it has been coated, does anything change with respect to the FiberWire ultra high molecular weight polythethylene, or does anything change with respect to the polyester?
MR. TAMBURO: Object to the form of the question. If you want to narrow it down, it has big properties, but that is a very broad question, the way it has been worded.
A The only thing I can say is that the changes are not altered. That is the whole idea of putting the coating on, and I hope it makes it more easier for when the surgeon actually ties the knot.
Q Is there anything else that changes?
A Not that I am aware of.
Q Okay. Now, does the tensile strength change before or after the coating?
MR. TAMBURO: Objection. Same objections a previously noted.

number 2 bobbin was before the coating, the stretching, and the bobbin after the coating stretching, is that --
A It does help.
Q It does help? Is there any other -- is there any carrier bobbins during this process?
A No.
Q There is only two bobbins, the beginning and the end?
A Yes.
Q What part of the yarn is stretched?
A There is no stretch. I have told you that. The only stretch taking place is through the pad.
Q Through the pad?
A And it is very minute. It is taking off the excess coating, and aligning all the film within that braid.
Q Is the speed at which the bobbin in moves itself the same as the output bobbin?
A Or -- it doesn't matter. I think it doesn't matter. They are bound to vary because that one is taking on more than that one over there.
Q The stretching process that you are referring to is the pads, are you saying that it

goes to a line yarn?
A It takes off any excess coating.
Q After that?
A Yes.
Q Now, the oven process that we have here, I think you referred to it as drying and the curing?
A That's correct.
Q Is the drying process here a technical curing process, or is it just drying the yarn?
MR. TAMBURO: Object to the form of the question.
A It does.
MR. BONELLA: What do you mean by that?
A Well, it is actually acting as a -- it dries out the coating, it burns off any excess chemicals as it comes through the bath, and it acts as actually purifies the new coating.
Q Purifies it? What do you mean by that?
A Without speculation, I would just imagine it is -- fills in any gaps and makes sure it is completely covered.
Q Is there material change that takes place during the -- is there any change that takes place on the coating during the drying process?
MR. TAMBURO: Objection to the form of the

question, and it calls for expert testimony.
A I don't know.
MR. BONELLA: You don't know? Right. Do you know the specification parameters for what tension that the yarn is under during the stretching process?
MR. TAMBURO: Object to the form of the question. That testimony -- mischaracterizing the prior testimony.
MR. BONELLA: I am sorry. Is the FiberWire under tension during the stretching process?
A Yes.
Q Where is the specification for that?
A It is written down in the process.
Q In the process. Okay. We need to go off the record.
(11.48 am)
OFF THE RECORD
(11.53 am)
MR. BONELLA: Mr. Hallett, when you referred to a pad, do you mean a rubber roller?
A Rubber pads.
Q Rubber pads. Not a roller?
A No.

Q Can you describe the pads?
A I can show you one, if you want.
Q Can you show me one? These are the rubber pads? (Pause)
These are rubber pads. This is a white one and a brown one?
A Yes.
Q Can you describe how they work?
A The braid is sandwiched in between, so these are put in between two brackets. The brackets are screwed down as tight as possible allowing just the minimum of braid to come through. So, therefore, that does allow a little bit of stretch and it takes off the excess Nusil. So, what we have is a brown pad and a white pad and the FiberWire goes between the two.
Q The two pads remove excess coatings?
A That's correct.
Q They subtely stretch the yarn?
A Under some tension, yes.
Q Do you know what that tension is?
A Yes.
Q Is it measurable?
MR. TAMBURO: Object to the form.
A No.

118

A Yes.
Q It was just the --
A That is done for the machine when it is set up for -- before they go in with a full run, to make sure the parameters are set up correctly within the machine.
Q It would be fair to say that -- wouldn't you have the input bobbin material, it goes through the stretching, coating, drying process, comes up on the take-up roller and a portion of that is sampled from over here, tested, and you can figure out what the knot pull, straight pull are, and if they are acceptable, then continue on with the process?
A That's correct.
Q Then the intermediate sample is taken at some point?
A That is done afterwards.
Q After the whole process is completed?
A Yes.
Q "Come over here, test the..."
A A percentage of that batch is tested.
Q Is tested, and that is the representative of the batch?
A Yes.
Q Then we have the measure stage testing?

119

A Yes.
Q After we do the measure stage, "Come up here, do the tests again"?
A Yes.
Q Couple more questions. After the FiberWire runs through the coating, stretching process, is there a way to measure the amount of coating that is on the FiberWire?
A No.
Q Pearsalls typically doesn't do that. Okay. When the -- each FiberWire goes through two of the coating stretching processes?
A That's correct.
Q Is there a way to tell how much coating is applied in the second process versus the first process?
A No.
Q Is it less than the first process? Generally?
A I don't think so.
Q You don't think so? Well, I don't know.
MR. TAMBURO: Objection, calls for speculation.
MR. BONELLA: For the samples that are tested in the stretch and intermediate stage

120

testing have they all undergone two cycles of the coating?
A They would have done, yes.
MR. BONELLA: If we could move to the final stage that would be great.
(12.40 pm)
OFF THE RECORD
(12.42 pm)
MR. BONELLA: Are we in the room where the time inspection and measuring process is performed?
A That's correct, yes.
Q What is the time inspection and measuring process performed in this room?
A It is wound to a final bobbin which is actually then sent out to the customer.
Q Any tensioning that is applied to the yarn during this process?
A Only through a clock which is actually giving the length, and the tension is given by the girls who actually control the speed of the bobbin which is taken off.
Q It is minimal tension?
A Very minimal.
Q Okay, and what is performed during this process?

121

A They are looking for any defects within the braid, and they are giving it a measured length.
Q A measured length on a spool?
A Yes.
Q What is the standard length?
A It depends on the size. On US2 I believe it is 500 metres.
Q And for US5?
A It is 250.
Q For the other sizes?
A A thousand, 500, it depends on which size.
Q For Size 0?
A That is a thousand metres.
Q 00 would probably be 2000. The 000 would be 3000. And 4000?
A 10000.
Q 0000 is 3000?
A 3000.
Q Okay, and after it undergoes this process then it goes back to the measuring in the QA in which measuring and testing is performed?
A It is labeled as well here.
Q It is labeled here? Okay. All right. Good. Thank you for your hospitality and showing us

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

HIGHLY CONFIDENTIAL

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
12th January 2006

Condensed Copy

244

affect the testing results, the knot strength testing results?
A Not generally it doesn't.
Q How about the testing? Can the testing show variations in the testing results?
A Sometimes, yes.
Q But you don't know for sure why the specifications changed?
MR. TAMBURO: Objection. Asked and answered.
A No.
MR. BONELLA: In Exhibit 316, do you see the second column under number 5 FiberWire lists a green product?
A Yes.
Q Similarly, Exhibit 317, the second column lists a green number 5 FiberWire. Do you see that?
A Yes.
Q Has Pearsalls manufactured green number 5 FiberWire for commercial use?
A No.
Q The products shown on Exhibit 316, have they all been manufactured for commercial use other than the green FiberWire, number 5?
A Yes.

245

Q How about Exhibit 317? Other than the green number 5 FiberWire, have all those other products been manufactured for commercial use?
A Whether they have been used for commercial use, I don't really know, but these have been given those references in case -- the product has been made, and that is how they would order it.
Q They would order it -- Arthrex orders it by the Pearsalls number?
A PS.
Q For example, Arthrex would order number 5 FiberWire but specifying DTPS 07?
A That's correct.
Q Next I will show you Exhibit 318. It is a two-page document produced to us this morning labeled, "Arthrex Products, Matrix of Label Product and Development Codes". Do you recognize Exhibit 318?
(DePuy Mitek Exhibit 318 marked for identification)
A Yes.
Q What is Exhibit 318?
A What is it?
Q Yes.
A It is a matrix both for the development and products for the use of FiberWire and TigerWire.

246

Q Have all the products listed in Exhibit 318 been sold for commercial use?
A I don't know.
Q How was this chart prepared?
A It was prepared by myself and one of the engineers at Arthrex.
Q Who? What Arthrex engineer?
A Tara Shanoville (Phonetic).
Q Why were -- how did you select certain products for entry into this matrix?
A Most of them would have been what they had been regarding.
Q What Arthrex had been ordering?
A Yes.
Q What about what Arthrex didn't order?
A Similarly they were listed.
Q Why were they listed?
A Because it may happen at some time or not.
Q Let's go through the chart, then. The first product, PS 30, has that been manufactured for commercial use?
A Yes.
Q How about the second product, PS C33? Has that been manufactured for commercial use?
A Yes.

247

Q How about PS 12/2? Has that been manufactured for commercial use?
MR. TAMBURO: Objection. Mike, is your question, have they been sold commercially, or -- because I think he testified that they are prepared to be sold commercially, so when you say, "Are they for commercial use", it is a little confusing, because they are all really for commercial use, but the question you may want to ask is; have they been sold commercially. I am not sure.
MR. BONELLA: What I am asking, Mr. Hallett, is, typically Pearsalls sells the -- the products just aren't samples, they are providing to Arthrex. They sell the product to -- they actually sell it to RK Manufacturing or to Arthrex?
A They would have gone -- originally they go to Arthrex.
Q They are sold to Arthrex?
A Yes.
Q Not RK?
A They go to RK, but if I made a development they normally go to Arthrex first for verification.
Q Development, but when they are sold, the

Q No you don't know?
A I don't know.
Q If you turn back to PR 8008, the 185/16 product with the definition of braid that we have been talking about being a braid of two different materials braided together, with that definition, does the 185/16 have a braid of two different materials braided together?
A No.
Q 185/16 is two different materials because it has one material in the core and one material in the cover?
A Yes.
Q Mr. Hallett, I will show you DePuy Mitek Exhibit 323. It is PR 7507 through 7512. Do you see the Dyneema property sheet that is attached to the document?
(DePuy Mitek Exhibit 323 marked for identification)
A Yes.
Q Have you ever seen that before? 7508 through 7512?
A Yes.
Q Yes?
A Yes.
Q Is that the market literature from Dyneema

with respect -- I am sorry. Is 7508 through 7512 marking literature from DSM on its Dyneema product?
A That's correct.
Q Does this describe the Dyneema that was used in FiberWire?
A Yes.
Q In the back it refers to the datasheet for SK65.
A Hmm hmm.
Q Was that SK65 ever used for FiberWire?
A Yes.
Q It was?
A Sorry. I think it was SK64.
Q That was used?
A Yes, because the finer sizes, I don't think they did it in an SK65.
Q Mr. Hallett, I am going to show you DePuy Mitek Exhibit 324. It is PR 6556. Is Exhibit 324 a letter that you received from Mr. Grafton on about November 16th, 1998?
(DePuy Mitek Exhibit 324 marked for identification)
A Yes.
Q It says in the letter to you that, "We...", referring to Arthrex, "... had tested the samples of the Dyneema material". Were those

samples 100% -- you see later down in the letter it says:
"Can you build a 25% Dyneema/75% polyester blend in a size 2 that is very flexible (like the existing suture or the ethicon sample) and send it to me to test".
Do you see that?
A Yes.
Q In the top paragraph does the sample of the Dyneema material, does that refer to a braid of 100% Dyneema?
A I can't remember.
Q Do you recall ever making a construction that was 100% ultra high molecular weight polyethylene for Arthrex?
A I can't remember.
Q In November '98 is that when FiberWire was first being developed?
A Yes.
Q What did you understand Mr. Grafton to mean when he said:
"Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".
What did you understand that to mean?
A Yes, that he wanted a braid which was

more -- not so stiff.
Q As the 100% ultra high molecular weight polyethylene?
A Yes.
Q He wanted Pearsalls to try to put polyester with --
A With the mixture.
Q With a braid. He wanted -- let me finish the question before you answer.
Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?
A Yes.
Q Next I will show you Exhibit 325. It is Bates number PR 6493. Do you recognize Exhibit 325 as a letter from you to Mr. Grafton from November 1998?
(DePuy Mitek Exhibit 325 marked for identification)
A Yes.
Q And the letter said:
"Please find enclosed a matrix of information of the samples that you took with you on your visit to Pearsalls, I will endeavour to proceed with the existing trial to match US2 Excel Braid

made by Ethicon, in Polyester construction. The next Poly/Dyneema samples should be with you by the end of the week".

Do you see that?

A Yes.

Q Then you list four samples and the yarn type, and the first one is Dyneema and the next three are poly/Dyneema?

A Yes.

Q Was the first sample 100% Dyneema?

A Yes.

Q The second through fourth samples were a blend of, or a braid of polyester and Dyneema?

A Correct.

Q The 100% Dyneema had higher -- did they all have the same size? Do you know if these were all the same size, number 2, or --

A I can't remember.

Q When Pearsalls was developing the FiberWire, was it trying to -- was it comparing it against the Ethicon XL product?

A I believe it was -- I don't know whether -- what it was comparing this to, but I was asked to make a braid compared with US5, a US5 diameter.

Q Yes, but do you see the reference to trying to match the US 2 XL braid made by Ethicon? Do you see that?

A Yes.

Q My question is; just generally in the development of FiberWire was Pearsalls comparing the products it was developing for FiberWire to Ethicon's XL products?

A Yes.

Q Was Pearsalls comparing the FiberWire products that it was developing to any other products during its development?

A Not that I can remember.

Q Next I will show you DePuy Mitek Exhibit 326. It is ARM2141 through 2147. First of all, I will see if you have any objections to the Arthrex Bates numbered document?

(DePuy Mitek Exhibit 326 marked for identification)

MR. TAMBURO: No objection.

MR. BONELLA: Mr. Hallett, is Mr. McLeod someone who works with you?

A He did work for us.

Q He has left Pearsalls?

A Yes.

Q When did he leave Pearsalls?

A Later part of last year. He still works at -- in Pearsalls.

Q What do you mean by that?

A He has been re-employed by a company called, "Novasive".

Q Is that a company that is related to Pearsalls?

A No.

Q So, Mr. McLeod is not employed by Pearsalls?

A No.

Q No he's not employed?

A He's not employed by Pearsalls.

Q But he was?

A He was.

Q Do you see in his letter he says the first lot of PA 26 was produced as a development sample, DTPA 26?

A Hmm hmm.

Q Then he goes on to say, in the second paragraph, or the third paragraph, that:

"Future orders will be supplied against the specification PA26B".

Do you see what?

A Yes.

Q In April 2001, is that when the -- it was decided to use the PA 6B code for number 2 FiberWire?

A It was decided, sorry?

Q It was decided to use the PA 6B code for number 2 FiberWire?

A Yes.

Q If you turn to page ARM2146, do you have that page? ARM2146? Do you see it says:

"The specification of the polyester is Type 712 and it is manufactured by KoSa GmbH & Company KG".

A Yes.

Q Is the polyester that Pearsalls has used for FiberWire always been manufactured by KoSa GmbH & Company KG?

A Yes.

Q Mr. Hallett, I will show you DePuy Mitek Exhibit 327, case number ARM2351, if you have no objections, Sal?

(DePuy Mitek Exhibit 327 marked for identification)

MR. TAMBURO: No objections.

MR. BONELLA: It says:

"The first shipment of 61,000 metres of new Blue FiberWire 2 is leaving today to RK".

MR. TAMBURO: Object to the form, and seeking expert testimony.
A I don't know.
MR. BONELLA: You don't know?
A No.
Q What type of variation would you see to make you think it was a big increase or a big decrease between the dye stage and the measure stage?
MR. TAMBURO: Object to form.
A It could be up to about a kilo.
MR. BONELLA: How much?
A One kilo.
Q One kilo?
A Yes.
Q It could be more than that?
A Hmm hmm.
Q Could it be up to two to three kilos?
A I wouldn't think so, no.
Q You wouldn't think so. I will show you Exhibit 339. It is Bates numbers PR 3730 through 3734 and it is entitled, "Pearsalls Sutures Results for Batch 26866". Mr. Hallett, do you recognize Exhibit 339 as a Pearsalls sutures Batch Record for batch 26866?

(DePuy Mitek Exhibit 339 marked for identification)
A Yes.
MR. TAMBURO: You don't have another copy of that?
MR. BONELLA: No. I couldn't truck over three copies of all of these. If you look at the Pearsalls sutures Works Order for Exhibit 399 it refers to the product code of 37G500500.
A Yes.
Q That is the product code for number 2 blue FiberWire?
A Yes.
Q Exhibit 339 is a record for batch 26866 for number 2 blue FiberWire?
A Yes.
Q If you look at the dye stage testing, the average knot strength, knot pull was 15.64?
A Hmm hmm.
Q Then if you look at the intermediate stage testing, it was 163990?
A Yes.
Q Then if you look at the measure stage testing, it was 15.03?
A Yes.
Q Do you know what account -- do you see

there between the dye stage and the intermediate stage it went up by over 1 kilo?
A Yes.
Q And then at the measure stage it went down over 1 kilo from the intermediate stage?
A Yes.
Q But the difference between the dye stage and the measure stage was 0.11 kilos?
A Yes.
Q Do you know what might account for the difference between the intermediate stage and the measure stage?
MR. TAMBURO: Object to the form.
A No.
MR. BONELLA: Do you know why the dye stage and the measure stage were about the same but the intermediate stage was about a kilo greater, over a kilo greater?
MR. TAMBURO: Object to form.
A No.
MR. BONELLA: Is that a concern, that level of variation?
MR. TAMBURO: Object to form.
A No.
MR. BONELLA: Why?

A Because I think you will see it reaches the requirements of that specific size.
Q You don't know what would cause it to go down between the intermediate stage testing and the measure stage testing?
MR. TAMBURO: Objection. Asked and answered.
A It could be the operator.
MR. BONELLA: Just the operator?
A Yes.
Q It could be how they tie the knot?
A Yes.
Q I will show you Exhibit 340. It is PR 4308 through PR 4321. It is Pearsalls sutures results for batch 25330. Do you recognize Exhibit 340 as the Batch Record for batch 5330?
(DePuy Mitek Exhibit 340 marked for identification)
A Yes.
MR. TAMBURO: Have you got another copy of that?
MR. BONELLA: No. If you go to the back you will see the product code is 25330?
A Correct.
Q Exhibit 340 is the batch record for number 2 FiberWire blue, batch 25330?

A Yes.
Q If you look at this document you will see that the dye average -- the average knot strength at the dye stage was 16.26; right?
A That's correct.
Q And then at the intermediate stage, the average knot pull strength was 16.53, right?
A Correct.
Q And then at the measure stage, the average knot strength was 16.75?
A That's correct.
Q So, between the dye stage and the intermediate stage, the difference in the knot pull, average knot pull was less than 0.3 kilos?
MR. TAMBURO: Object to form.
A Correct.
MR. BONELLA: And the difference between the average knot strength between the intermediate stage and the measure stage was less than 0.3 kilos as well; right?
A That's correct.
Q Are these numbers, this 16.26, 16.53, 16.75, are they considered to be all about the same, based on the tolerances?
A That's right.

Q Next I will show you Exhibit 341. It is PR 3778 through 3791 entitled, "Pearsalls Sutures Results for Batch 5899", do you recognize Exhibit 341 as the Batch Record results for batch 5899?
(DePuy Mitek Exhibit 341 marked for identification).
A Yes.
Q Would you turn to the Work Order on PR 3791? Do you see the product code is 35G500?
A Correct.
Q Batch 25891 is for number 2 blue FiberWire?
A Yes.
Q If you look at the testing you will see that the average knot pull strength at the dye stage was 15.61, correct?
A That's correct.
Q The average knot pull strength at intermediate testing was 14.83?
A That's correct.
Q The average knot strength at the measure stage was 16.87?
A That's correct.
Q Do you know what would account for the decrease in average knot pull strength between the dye stage and the intermediate stage?

MR. TAMBURO: Object to form and seeking expert testimony. Do you have a copy for counsel, Mr. Bonella?
MR. BONELLA: I have one copy of the Batch Records. I didn't even bring one for me.
A That is the operator testing.
Q Operator testing?
A Hmm hmm.
Q Do you know what would account for the increase in average knot pull strength between the intermediate stage and the measure stage?
MR. TAMBURO: Same objection.
A Yes.
Q What is that?
A Because it has been coated.
Q Coated?
A Hmm hmm.
Q If it increases when it is coated, we saw other ones where it decreased when it was coated?
A Very slightly.
Q In Exhibit 339, the average knot pull decreased between intermediate and measure from 16.9 to 15.53, right? That was a decrease of 1.4, right?
A Yes.
Q Do you know why that would be?

A No. Operator.
Q What accounts for the -- so, with Exhibit 341 you are saying the decrease between the dye and the intermediate stage was due to coating?
MR. TAMBURO: Objection. Asked and answered.
A The increase.
MR. BONELLA: I am sorry, the increase, but didn't it go from -- it was 15 -- in Exhibit 341, the average knot pull in dye was 15.361, right?
A Yes.
Q That is before coating?
A Hmm hmm.
Q And the average knot pull at the intermediate stage was 14.483, right, and that is after coating?
A Hmm hmm.
Q What caused the knot pull to go down from the dye stage to the intermediate stage?
MR. TAMBURO: Objection, calls for expert testimony, asked and answered. Calls for speculation.
A I don't know.
MR. BONELLA: You don't know?

348

A No.
Q How do you know at the measure stage it was -- in Exhibit 341 it was 16.482; right?
A So it is increased.
Q Check numbers. But how do you know -- it is increased. There is nothing done with the suture between the intermediate stage and the measure stage that would change the property of the suture; right?
A Hmm hmm.
Q Right?
A Yes.
Q Yes, I am correct?
A Yes, you are correct.
Q How do you know which one's right, the decreased one at the intermediate stage or the increased one at the end stage?
MR. TAMBURO: Calls for expert testimony and object to the form.
MR. BONELLA: Or were they all about the same?
A They all vary.
Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the

349

other?
MR. TAMBURO: Objection, calls for expert testimony and speculation.
A Yes.
MR. BONELLA: That's correct?
A Yes.
MR. TAMBURO: Mike, this is the once-passed coating sample of US2 FiberWire. We don't have a Bates number but I will send you a Bates number by e-mail. It is a little capsule labeled, "Sample Pearsalls Limited blue FiberWire single coating 15 metres US2 batch number 28790".
MR. BONELLA: Okay. We will mark it as DP342 and ask Mr. Hallett if you can identify DePuy Mitek Exhibit 342, or take counsel's representation that it is number 2 blue FiberWire that has been run through the coating, stretching and drying process only one time. Is that correct?
(DePuy Mitek Exhibit 342 marked for identification)
MR. TAMBURO: That is my understanding yes.
MR. BONELLA: Can he testify to that? Does he know?

350

MR. TAMBURO: I think he knows only what I know. He wasn't there watching it when it was done.
MR. BONELLA: All right. I will take your representation that it is what it is.
I will show you DePuy Mitek Exhibit 343. It is a three-page document test recorded summary and sign-off sheet from Arthrex. Sal, do you have any problems in me showing him Exhibit 343? It was disclosed to J&J as non-contentious.
MR. TAMBURO: No objection.
MR. BONELLA: Mr. Hallett, I am showing you Exhibit 343. I believe it has Brian Hallett's writing on the first page, I believe it is a document from Arthrex. Have you ever seen this document before?
(DePuy Mitek Exhibit 343 marked for identification)
A Yes.
Q You have?
A Hmm hmm.
Q When did you see it?
A Sometime last year.
Q And why did you see it?
A I think it was describing or showing the

351

test procedure for doing a braid load on the loops.
Q On what?
A On the loop.
Q If you look at the top it says the description of the procedure on the first page is number 2 FiberWire 2174 coated and uncoated USIPG dyed, and the date is February 16, '04, and the type of test it says, knot tiedown, and it says:
"The test objective: To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture".
Do you see that?
A Hmm hmm.
Q The test method is described as:
"The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture

BROOKSTEIN DECLARATION
EXHIBIT 6

Arthrex

November 16, 1998

Brian Hallett
Pearsalls Sutures
Tancred Street, Taunton
Somerset TA1 1RY, England

FAX 011441823336824

Dear Brian:

We have tested the samples of the Dyneema material I got from you when I was at Pearsalls. They have very good tensile strength but as you mentioned they are larger in diameter than the size 2 suture we presently use. We do need for our test record more info on the 4 samples. If you could give me some basic specifications for our records I would appreciate it.

Can you build a 25% Dyneema / 75% polyester blend in a size 2 that is very flexible (like the existing suture or the ethicon sample) and send it to me to test? If we can get this blend correct, we will have a terrific advancement in suture for our soft tissue anchors.

Thank you

Don Grafton
V. P. Engineering
Arthrex Inc.

DEPUY MITEK
EXHIBIT 324
04cv12457

BROOKSTEIN DECLARATION
EXHIBIT 7

TO :Arthrex

ATTN: Don Grafton

FROM : Brian Hallett

DATE : 16/11/98

SUBJECT : POLYESTER - DYNEEMA -(Braids)

Dear Don,

Please find enclosed a matrix of information of the samples that you took with you on your visit to Pearsalls , I will endeavour to proceed with the existing trial to match the US2 Excel Braid maid by Ethicon, in Polyester construction.
The next Poly/Dyneema sample should be with you by the end of the week

Yarn	Dt-no	Runnage Mt/ Kg	St/pull KG	Diameter MM	Extention %	PPI
Dyneema	DAOI	3034	23.12	0.714	24.39	46
Poly/Dyneema	PA13	2984	36.27	0.702	18.33	48
Poly/Dyneema	PA14	3331	34.95	0.639	18.83	48
Poly/Dyneema	PA14 Stretch	3469	36.41	0.628	14.32	48

Kind regards

Brian Hallett
Product Development Manager

DEPUY MITEK
EXHIBIT 325
04cv12457

BROOKSTEIN DECLARATION
EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

_______________________________/

DEPOSITION OF:	PETER DREYFUSS
DATE:	September 16, 2005
TIME:	8:59 a.m. to 1:54 p.m.
LOCATION:	The Ritz Carlton Golf Resort 2600 Tiburon Drive Naples, FL 34112
TAKEN BY:	Plaintiff
REPORTER:	Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER:	Les Smoak, CLVS

94

do on sutures.
Q. But Arthrex doesn't specifically test for how much coating has been applied on FiberWire sutures from Pearsalls?
A. No, not that I'm aware of.
Q. Has Arthrex ever rejected a batch of bulk sutures based on the amount of coating that's been applied to any FiberWire sutures?
A. Not that I know of.
Q. Okay. And then -- Okay. Now back to ARM 8784 in Exhibit 102, we've stretched and coated the suture or the braid, and what's the next step?
A. It looks -- final inspection and measuring, which would be QC.
Q. And how is that final inspection QC performed?
A. There's, as I understand, there's various steps. Mechanical measuring, and there's a -- whatever -- by feel, measuring for any imperfections.
Q. Popping maybe? Are you familiar with that term?
A. Not exactly.
Q. Okay.
A. Just making sure the suture is homogenous, consistent, and strong.
Q. Now you said mechanical measuring. What kind of mechanical measuring is used in the inspection process for

95

Arthrex's FiberWire sutures?
A. There's a -- they actually measure the diameter per a certain procedure or a certain approved protocol that you measure the diameter at several places, several locations along a certain piece of suture to get an average diameter.
Q. Does Arthrex provide specifications to Pearsalls for the inspection process of its FiberWire sutures?
A. Yes.
Q. And what specifications are those?
A. Drawing -- on the drawing specifications, I would assume.
Q. Okay.
A. And possibly in an inspection procedure that we have written up in a document form.
Q. Okay. And once the braid or the bulk suture has been inspected and measured, what happens next?
A. If approved, I would assume it would be either -- well, if it's part of an order, I would assume it's then be shipped to the customer, which would be ...
Q. And then that customer -- Strike that.
The braiding process that we've talked about with respect -- Strike that.
The manufacturing process that we've talked about with respect to ARM 8784 in Exhibit 102, that testimony as

96

it related to the 16-carrier bobbin applies to Arthrex's FiberWire No. 2 as sold in AR-7201; right?
A. Correct.
MR. FALKE: Why don't we break for lunch.
MR. TAMBURO: Sounds good.
VIDEOGRAPHER: Going off the record. We're off
(A lunch break was held from 11:47 a.m. to 12:47 p.m.)
VIDEOGRAPHER: Back on the record.
BY MR. FALKE:
Q. Okay, Mr. Dreyfuss, do you want to look at Exhibit 120 for a minute. The coating that's shown in Exhibit 120 and the bath of the coating, is that bath comprised of 100 percent MED-2174?
MR. TAMBURO: Object to the form.
A. I believe it is, yes.
Q. Okay. So there's no solvent or any other material used possibly to dissolve the coating?
A. I'm not aware of it, no.
Q. Okay. But you understand the coating -- the bath of MED-2174 as used in the coating process for Arthrex's FiberWire sutures to be 100 percent MED-2174?
A. I believe so.
Q. Also, if we could go back -- That's okay. I'd like you to take that sheet of paper there in front of

97

you, and if you could, could you draw a cross-section of Arthrex's No. 2 FiberWire?
A. I can -- I can try, yes.
Q. And list, please -- you know -- the various materials and what not. And I'm going to mark your drawing of a cross-section of Arthrex's No. 2 FiberWire with Exhibit No. 121.
(DePuy Mitek Exhibit No. 121, drawing of Peter Dreyfuss of the Approximate Cross-Section of Arthrex 2-0 FiberWire, was marked for identification.)
A. I luckily got eight. Oh. I approximated the numbers.
Q. Okay. Did you say you drew eight?
A. I drew an eight -- a version of an eight-carrier braid.
Q. Okay. And that would be a cross-section then of Arthrex's 2-0 FiberWire suture?
A. Yes.
Q. Okay. So we're going to remark Exhibit 121 as a drawing of Arthrex's 2-0 FiberWire suture; is that correct?
A. Yes.
Q. Okay. And if you could just label that and initial and date it, please.
A. (Witness complying).

98

Q. And I don't know if you did, but could you please label the core and the cover?
A. Yes, I did.
Q. Okay.
A. I was doing a core with three parts to represent the No. 2 suture. But since it's an 0, I'm not exactly sure how many yarns are made up of the core, but they're all UHMWP --
Q. Okay.
A. -- if that's acceptable.
Q. Okay. Yeah. Let me just take a look at it, please.
Okay. So but other than the core, which you're not quite sure of how many yarns make up the core on the 2-0, this outside accurately represents the cover or the sheath of the Arthrex 2-0 FiberWire?
A. Yes.
Q. Okay. And as you have shown, going around the cover or the sheath, the materials alternate PET, ultra high molecular weight polyethylene, PET, ultra high molecular weight polyethylene, et cetera?
A. Yes.
Q. Okay. Now within the sheath or the cover -- Well, first could you just label the sheath and the cover for me?

99

A. (Witness complying).
Q. Are the individual yarns in the cover or sheath of the Arthrex 2-0 FiberWire as shown in 121 in contact with each other, meaning is the ultra high molecular weight polyethylene yarn connected to the neighboring PET yarn?
MR. TAMBURO: Object to the form.
A. They're all interdigitated. I'm sure there's contact between them.
Q. Intertwined?
A. Yes.
Q. Okay. So there is contact then between the neighboring or adjacent PET and ultra high molecular weight --
A. Yes.
Q. -- polyethylene yarns and the sheath or cover?
A. Yes.
Q. Okay. Next, if you could, could you please draw a cross-section of Arthrex's No. 2 FiberWire?
And -- I'm sorry. But before we go on, does Exhibit 121 reflect the construction or the structure of the 2-0 FiberWire as it's always been?
A. To the best of my knowledge, yes.
Q. Okay. So the construction with the structure as shown in 121 of a 2-0 FiberWire suture hasn't changed over

100

time? Ever since Arthrex is manufacturing a 2-0 FiberWire, it's been using this configuration as shown in 121?
A. Yes.
Q. Okay.
A. (Witness complying).
Q. And I'm going to mark your drawing of Arthrex's No. 2 FiberWire suture as DePuy Mitek Exhibit 122.
(DePuy Mitek Exhibit No. 122, drawing of Peter Dreyfuss of the Approximate Cross-Section of No. 2 FiberWire, was marked for identification.)
Q. Can I take a look at it, please?
A. Yes.
Q. Okay. And so this shows a core made up of three ultra high molecular weight polyethylene yarns twisted together and then a cover or sheath composed of alternating yarns of ultra high molecular weight polyethylene and PET; is that right?
A. Correct.
Q. And the PET and ultra high molecular weight polyethylene that make up the sheath or cover of Arthrex's FiberWire No. 2 are in direct contact with each other; is that right?
A. Yes.
Q. Okay. And they're intertwined around each other;

101

right?
A. They're braided.
Q. Okay. Is that intertwining or --
A. Yes, they're ...
Q. Okay. And does Exhibit 122 accurately reflect the construction of Arthrex's FiberWire No. 2 currently and since its release or since it was first sold by Arthrex?
MR. TAMBURO: Object to the form.
A. I believe so.
Q. Okay. Could you mark or title Exhibit 122?
A. (Witness complying).
Q. And next I was going to ask you to draw a cross-section of the No. 5 Arthrex FiberWire suture, which I believe is the same as Exhibit 122 that you have just drawn with the exception of possibly the number of yarns that comprise the core; is that right?
A. I believe that would be correct.
Q. Okay. And -- but the outside of the cover or sheath of the Arthrex FiberWire No. 2 is the same as the cover or sheath of the Arthrex FiberWire No. 2; right?
A. In the manner of braiding, yes.
Q. Right.
MR. TAMBURO: Object to the form.
Q. In the manner as you have shown in Exhibit

No. 122?
A. Yes.
Q. I misspoke there, but the outside or the cover of the Arthrex FiberWire No. 5 is the same as the cover or sheath of the Arthrex FiberWire No. 2; is that correct?
A. That's correct.
Q. Okay. The same in terms of configuration and contact and intertwining; right?
A. Yes.
Q. Okay. Next, if I can ask you to draw the cross-section of Arthrex's No. 0 FiberWire.
A. Let's see.
Q. And I believe you testified earlier, and correct me if I'm wrong --
A. Twelve.
Q. -- that there's twelve carriers?
A. Correct.
Q. Okay. And I also believe you testified earlier that you weren't sure about how many yarns make up the core in Arthrex's Size 0 FiberWire; is that right?
A. That's correct.
Q. Okay.
A. I'm sorry; would you give me the number again?
MR. TAMBURO: Here.
A. All right.

Q. Now I'm going to mark your drawing of a cross-section of Arthrex's No. 0 FiberWire with DePuy Mitek Exhibit 123.
(DePuy Mitek Exhibit No. 123, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 0 FiberWire, was marked for identification.)
Q. And I believe what you've drawn in Exhibit 123 is that the cover or sheath of the Arthrex No. 0 FiberWire has alternating yarns of PET and ultra high molecular weight polyethylene; is that right?
A. Correct.
Q. And that -- and that those neighboring yarns in the sheath or cover are in contact with each other?
A. Correct.
Q. And in the same configuration and intertwining manner as Exhibits 122 and 121?
A. Correct.
Q. Okay. Could you draw for me a cross-section of Arthrex's FiberWire 3-0 suture? I believe you testified earlier that it's eight carriers.
A. Thank you.
Q. And I'm going to label your cross-section drawing of Arthrex's FiberWire No. 3 suture with DePuy Mitek Exhibit 124.
(DePuy Mitek Exhibit No. 124, drawing of Peter

Dreyfuss of the Approximate Cross-Section of Size 3-0 FiberWire, was marked for identification.)
Q. And just so the record's clear, all these hand drawings that you have done so far, when it says UHMW, that means ultra high molecular weight polyethylene?
A. Correct.
Q. Okay. And what you've shown is that Arthrex's No. 3-0 FiberWire has alternating yarns of PET and ultra high molecular weight polyethylene?
A. Correct.
Q. And that those neighboring yarns and the sheath or cover contact each other?
A. Correct.
Q. And they're in the same -- you know -- intertwining manner as Exhibits 123, 122, and 121?
A. Correct.
Q. And now if you could just draw for me a cross-sectional drawing of Arthrex's 4-0 FiberWire suture, please. And I'm going to mark your drawing of Arthrex's 4-0 FiberWire suture with DePuy Mitek Exhibit 125.
A. (Witness complying).
(DePuy Mitek Exhibit No. 125, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 4-0 FiberWire, was marked for identification.)
Q. And I believe what you've shown in Exhibit 125 is

that, one, there's no core in the 4-0 FiberWire; right?
A. Correct.
Q. And that the sheath or cover is made up of intertwining yarns of ultra high molecular weight polyethylene and PET?
A. Correct.
Q. And that the neighboring yarns within the cover or sheath are in contact with each other?
A. Correct.
Q. Okay. Do Exhibits 123, 124, and 125 show not only the present-day but the configuration of the FiberWire sutures as sold in the past?
A. Yes, to the best of my knowledge and --
Q. In other words, there hasn't been any different configurations of Arthrex's 0, 3-0, and 4-0 FiberWire sutures?
A. I'm not for certain on the 4-0.
Q. Okay. But for the 2-0 and the -- or for the 0 and the 3-0 you are?
A. Yes.
Q. Okay. And I don't think I asked you this, but in Exhibit 125, the alternating sheaths -- alternating yarns and the sheath or cover are in intertwining contact like Exhibits 124, 123, 122, and 121?
A. Yes.

106

Q. Okay. Now what I'd like you to draw is a cross-section of Arthrex's TigerWire suture.
A. Okay. Which size? Actually, there's --
Q. That's a good question. How many sizes of TigerWire are there?
A. No, technically, there's only one.
Q. Okay. Is that a No. 2 size?
A. Correct.
Q. Okay. So just to rephrase, can you please draw a No. 2 TigerWire as sold by Arthrex?
A. (Witness complying).
Q. And I'm going to mark your drawing of No. 2 TigerWire as sold by Arthrex with DePuy Mitek Exhibit 126.
(DePuy Mitek Exhibit No. 126, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 2 TigerWire, was marked for identification.)
Q. Do you know how many carriers are in the Arthrex No. 2 TigerWire?
A. Sixteen.
Q. Sixteen. So the configuration of the sheath or cover in Arthrex's No. 2 TigerWire is exactly the same as the sheath or cover as Arthrex's No. 2 FiberWire with the exception that one of the PET carriers has been replaced with a black nylon carrier?
A. Correct.

107

Q. Okay. So the sheath has alternating yarns made up of ultra high molecular weight and polyester or PET with the exception of one carrier that is black nylon?
A. Correct.
Q. Okay. And the adjacent yarns in the sheath are in contact with each other in the same intertwining manner as Exhibits 125, 124, 123, 122, and 121?
A. Correct.
Q. Okay. All right. Thank you.
Okay. Now I'd like to talk about FiberTape. Could you explain to me the process that Pearsalls goes through to manufacture FiberTape from the stage of individual yarns?
Actually -- Do you know what? I might have a document here that would help you out.
I'm going to show you what's being marked as DePuy Mitek Exhibit 127. It's a document with Bates numbers ARM 8847 through 9091.
One is double-sided; one isn't. That one goes to Sal. No. I'm sorry. That one goes to Sal.
Okay. We're talking about Exhibit No. 127.
(DePuy Mitek Exhibit No. 127, Technical File Arthrex FiberWire Volume 2, was marked for identification.)
Q. Have you seen Exhibit 127 before?

108

A. Not to my knowledge, no. Not ...
Q. If you could turn to Page ARM 9003. Now you can -- I'm sorry; it's the page before also, ARM 9002.
I'm going to ask the question again. If you need to reference this page, go right ahead. Can you explain to me the process that Pearsalls goes through to manufacture Arthrex's FiberTape?
A. In short, a tape component is -- They use the -- a braiding machine. But the carriers are configured in such a way that the braids don't -- the ends of the carriers don't actually cross, and, therefore, it's an open braid which, when it's taken up on the takeup spool, it flattens out, makes a tape. That tape is then incorporated -- stitched into a piece of FiberWire suture along its length with a length of -- the length of FiberWires on the ends which have no tape. The middle portion of the construct is FiberWire and FiberTape interstitched, and the ends and the FiberTape ends within the FiberWire, and then there's ends of FiberWire outside of that.
Q. Okay. So does Arthrex's FiberTape include an Arthrex No. 2 FiberWire suture?
A. Yes.
Q. And does it include the Arthrex FiberWire No. 2 suture as depicted in Exhibit 122?

109

A. Yes.
Q. Can you just draw for me, please, the cross-section of an Arthrex FiberWire Tape as --
A. Can I -- May I simplify it? Representative of FiberWire and tape without all ...
Q. Sure. You can start about that, and if I'm confused or need more, then I'll let you know. But you can start with that.
MR. TAMBURO: I'm going to object to this line of questioning regarding FiberTape as outside the scope of the notice, which seems to be limited to FiberWire sutures.
MR. FALKE: Well ... I think we defined in our first set of either documentary requests or Interrogatories as FiberWire including FiberWire or any product that includes FiberWire, but your objection is -- you know -- it's your objection.
MR. TAMBURO: I thought I heard a different definition today of FiberWire suture that would not include FiberWire Tape.
MR. FALKE: Right. But I think the notice was probably using the definitions of the other discovery, not necessarily definitions of mine, but --
MR. TAMBURO: Fine. I just wanted to note my objection.

122

Q. What is FiberStick, sold under AR-7209?
A. FiberStick is a length of FiberWire that has a -- a long length of it that is tipped or stiffened with the Loc-Tite, and it makes it easier to perform certain actions with.
Q. Other than the difference in the length of stiffening on the end of FiberStick, is there any other difference in any way between FiberStick AR-7209 and the blue FiberWire in AR-7201?
A. Just the overall length is longer.
Q. Okay. So is the structure and configuration in FiberStick AR-7209 the same as the No. 2 FiberWire in Exhibit 122?
MR. TAMBURO: Object to form.
A. Yes.
Q. Does the No. 2 FiberSnare in AR-7209SN have the same structure and configuration as the No. 2 FiberWire in Exhibit 122?
MR. TAMBURO: Same objection.
A. I believe so. I'm not for sure on this one product.
Q. Okay. What's your understanding of what FiberSnare is as sold under AR-7209SN?
A. No, I only understand -- I'm -- I'm familiar on the surface with this product, and I've seen different

123

appearances of it, so I can't answer for sure. It doesn't appear -- I've seen it in appearance it looked a little different, so I don't want to answer --
Q. Okay.
A. -- incorrectly.
Q. Okay. Does the No. 2 TigerStick of AR-7209T the same -- have the same structure and configuration as the No. 2 FiberWire in Exhibit 126?
MR. TAMBURO: Object to form.
A. Yes.
Q. Do you understand what I'm saying when I say structure and configuration?
A. Yes, I interpret it as approximately the same makeup.
Q. As that shown?
A. As that shown.
Q. Okay. Does the No. 5 FiberWire AR-7210 have the same structure -- Strike that.
Does the No. 5 FiberWire in AR-7210 have the same structure and configuration as the No. 5 FiberWire shown in Exhibit 122?
MR. TAMBURO: Objection to form.
A. Yes.
Q. And does the No. 5 FiberWire AR-7211 have the same structure and configuration as the FiberWire shown in

124

122 -- Exhibit 122?
MR. TAMBURO: Object to form. And it mischaracterizes the exhibit.
A. Yes.
Q. Does the No. 5 FiberWire sold with AR-7219 have the same structure and configuration as the suture shown in Exhibit 122?
MR. TAMBURO: Same objection.
A. Yes.
Q. Okay. Does the No. 5 TigerWire shown or sold with AR-7219 have the same structure and configuration as the No. 2 TigerWire in Exhibit 126?
MR. TAMBURO: Object to form.
A. Yes.
Q. And the No. 2 FiberWire sold under AR-7219, does that have the same structure and configuration as the No. 2 FiberWire shown in Exhibit 122?
MR. TAMBURO: Same objection.
A. Sorry. Did you say FiberWire?
Q. Yeah. Do you want me to repeat it?
A. Please.
Q. Okay. And the No. 2 FiberWire sold under AR-7219, does that have the same structure and configuration as the No. 2 FiberWire shown in Exhibit 122?
MR. TAMBURO: Same objection.

125

A. Yes.
Q. And the No. 2 FiberWire sold under AR-7220 and AR-7221, do they have the same structure and configuration as the 2-0 suture shown in Exhibit 121?
MR. TAMBURO: Object to form.
A. Yes.
Q. And the No. 2 -- excuse me. Does the 2-0 FiberStick have the same structure -- Strike that.
Does the 2-0 FiberStick in AR-7222 have the same structure and configuration as the 2-0 FiberWire shown in Exhibit 121?
MR. TAMBURO: Same objection.
A. Yes.
Q. Does the 3-0 FiberWire in AR-7225 and AR-7227-01 and -02 have the same structure and configuration as the 3-0 FiberWire shown in Exhibit 124?
MR. TAMBURO: Same objection.
A. Yes.
Q. Does the 4-0 FiberWire sold under AR-7228, 7230-01, and 7230-02 have the same structure and configuration as the 4-0 FiberWire suture in Exhibit 125?
MR. TAMBURO: Same objection.
A. Yes.
Q. Does the 4-0 FiberLoop in AR-7229-12 and AR-7229-20 have the same structure and configuration as

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

Arthrex, Inc., a Delaware Corporation,

Defendant.

CIVIL ACTION NO. 04-12457 PBS

CONTINUATION DEPOSITION OF: PETER DREYFUSS

DATE: December 7, 2005

TIME: 8:03 a.m. to 1:21 p.m.

LOCATION: The Staybridge Suites
4805 Tamiami Trail North
Naples, FL

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Michael Sturdevant, CLVS

74

Q. And if you see in the second paragraph, second sentence, it says, "The Black/White Suture commonly known as TigerWire has a blend of nylon and the ultra high molecular weight polyethylene." Do you see that?
A. Yes.
Q. And if you skip a sentence, it says, "In place of the nylon, a silk suture will be used." Do you see that?
A. Yes, I do.
Q. Is the only difference between Arthrex's TigerWire and Arthrex's FiberWire with silk is the silk suture is used in place of the nylon marker strand in Arthrex's TigerWire product; is that right?
MR. SABER: Object; vague and confusing question.
Q. Do you understand the question?
A. I understand, I believe, from what I read here that that is true.
Q. And the last time we were here, you described the design and construction of the TigerWire product. Do you remember that?
A. Yes, I understand that.
Q. What is the purpose of the nylon marking strand in Arthrex's TigerWire product?
A. Identification. Visual identification.
Q. Is there any other purpose to the nylon marking strand in Arthrex's TigerWire product?

75

A. That's the primary purpose. I'm not sure if there's secondary purposes, per se.
Q. Does the introduction of a nylon marking strand in the TigerWire product affect any of the physical characteristics of the TigerWire product?
A. Affect in --
Q. Other than the visual distinction that you can see with the introduction of a nylon marking strand, does the nylon marking strand in TigerWire affect any other characteristic of the braided suture?
A. Yes.
Q. What is -- what?
A. Minute differences in its feel and strength, characteristics.
Q. But you would describe them as minute differences?
A. Not enough to cause it not to become a product.
Q. Can you explain that?
A. It's --
Q. In other words, the introduction of the nylon marking strand doesn't affect any of the marketing qualities or engineering qualities that make FiberWire FiberWire; does that make sense?
MR. SABER: Objection; vague.
A. It -- They are comparable.

76

Q. But they show -- But a No. 2 TigerWire, for instance, and a No. 2 FiberWire show very similar knot strength, tensile strength, handleability, and what not, all of the characteristics that define FiberWire?
A. I believe so.
Q. Okay. And is that true also with the introduction of silk rather than a nylon marker?
A. I don't know.
Q. Do you know whether the silk used in the FiberWire with silk suture affects any of the characteristics of the suture?
A. No, I don't.
Q. Based on your understanding of Arthrex's FiberWire with silk product, do you think you would be able to draw a cross-section of the suture?
A. I -- No.
Q. No? But as far as you know, the only difference between the TigerWire and a FiberWire with silk is instead of the nylon, it's a piece of silk?
A. That would be a good generalization.
Q. Okay. And Don Grafton would know this information?
A. I believe so, yes.
(DePuy Mitek Exhibit No. 142, Design History File for FiberWire 3-0 and 4-0, ARM 6580 through 6950, was

77

marked for identification.)
Q. I'm going to hand you a document labeled DePuy Mitek Exhibit 142. It's a document with Bates numbers ARM 6580 through 6950.
Have you seen Exhibit 142 before?
A. I believe so.
Q. And what is DePuy Mitek Exhibit 142?
A. The Design History File for FiberWire new sizes -- new sizes of FiberWire.
Q. And what new sizes for FiberWire?
A. 3-0 and 4-0.
Q. Do you have any reason to believe the information in Exhibit 142 is inaccurate?
MR. SABER: Objection; overbroad.
A. No, I don't.
MR. FALKE: I'm just trying to authenticate the document.
MR. SABER: No, I have no problem with you authenticating the document, but I -- you know -- this is, again, a document of hundreds of pages. And to ask him to -- a generalized question like that I think is kind of unfair.
BY MR. FALKE:
Q. Do the instructions for use that are included with all of Arthrex's FiberWire product indicate that the

BROOKSTEIN DECLARATION
EXHIBIT 9

Ap 154

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 2, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

Matthew S. Goodwin
(Signature)

December 2, 1992
(Date of Signature)

GROUP 1500

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

The braided suture is made up of <u>multifilament yarns</u>. A multifilament yarn is a <u>bundle</u> of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be <u>bundled</u> to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct <u>intertwining</u> contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a <u>multifilament</u> yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The <u>only</u> component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the <u>essence</u> of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches <u>randomized</u> braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a <u>structured</u> braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,

Matthew S. Goodwin

Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2794
December 2, 1992

BROOKSTEIN DECLARATION
EXHIBIT 10

Marks' Standard Handbook for Mechanical Engineers

Revised by a staff of specialists

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Eighth Edition

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MARKS' STANDARD HANDBOOK FOR MECHANICAL ENGINEERS

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First Edition *Eleven Printings*	Third Edition *Seven Printings*	Fifth Edition *Seven Printings*	Seventh Edition *Fifteen Printings*
Second Edition *Seven Printings*	Fourth Edition *Thirteen Printings*	Sixth Edition *Eight Printings*	

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It was set in Janson by University Graphics, Inc.

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The editors and the publishers will be grateful to readers who notify them of any inaccuracy or important omission in this book

Table 1. Fiber Properties*

Kind	Source	Length of fiber, in.	Width or diam of cells, microns	Specific gravity	Moisture regain,‡ percent	Chemical description	Principal uses
Cotton	Plant seed hair	5/8–2	8–27	1.52	8.5	Cellulose	Industrial, household, apparel
Jute†	Plant bast	50–80	15–20	1.48	13.7	Lignocellulose	Bagging, twine, carpet backing
Wool	Animal	2–16	10–50	1.32	17	Protein	Apparel, household, industrial
Viscose	Manufactured	Any	8–43	1.52	11	Regenerated cellulose	Apparel, industrial, household
Cellulose acetate	Manufactured	Any	12–46	1.33	6	Cellulose ester	Apparel, industrial, household
Nylon	Manufactured	Any	8	1.14	4.2	Polyamide	Apparel, industrial, household
Casein	Manufactured	Any	11–28	1.3	4.1	Protein	Apparel
Flax†	Plant bast	12–36	15–17	1.5	12	Cellulose	Household, apparel, industrial
Hemp†	Plant bast	.....	18–23	1.48	12	Cellulose	Twine, halyards, rigging
Sisal†	Plant leaf	30–48	10–30	....	....	Lignocellulose	Twine, cordage
Manila†	Plant leaf	60–140	10–30	....	....	Lignocellulose	Rope, twine, cordage
Ramie†	Plant bast	3–10	24–70	1.52	....	Cellulose	Household, apparel, seines
Silk	Silkworm	Any	5–23	1.35	11	Protein	Apparel, household, industrial
Glass	Manufactured	Any	3	2.5	0	Fused metal oxides	Industrial, household
Dacron	Manufactured	Any	8	1.38	0.4	Polyester	Apparel, industrial, household

1 in = 0.0254 m; 1μ = 10^{-6} m. The more up-to-date term for the micron (μ) is the micrometer (μm).

*Adapted from Smith, Textile Fibers, *Proc. ASTM*, 1944; Appel, A Survey of the Synthetic Fibers, *Am. Dyestuff Reporter*, 34, 1945. pp. 21–26; and other sources.

†These fibers are commercially used as bundles of cells. They vary greatly in width. Width figures given are for the individual cells.

‡In air at 70°F and 65 percent relative humidity.

Table 2. Tensile Properties of Single Fibers*

Fiber	Breaking tenacity, gpd	Extension at break, percent	Elastic recovery at corresponding strain, percent	Elastic modulus,† gpd
Glass	6.0–7.3	3.0–4.0	100 at 2.9	200–300
Fortisan (rayon)	6.0–7.0	6	100 at 1.2	150–200
			60 at 2.4	
Flax	2.6–7.7	2.7–3.3	65 at 2	
Nylon 6, 6	4.6–9.2	16–32	100 at 8	25–50
Nylon 6	4.5–8.6	16–40	100 at 8	25–50
Silk	2.4–5.1	10–25	92 at 2	75–125
Saran	1.1–2.3	15–25	95 at 10	
Cotton	3.0–4.9	3–7	74 at 2	50–100
Steel (90,000 psi T.S.)	0.9	28	....	300
Steel (music wire)	3.5	8	....	300
Viscose rayon	1.5–5.0	15–30	82 at 2	50–150
Wool	1.0–1.7	25–35	99 at 2	25–40
Acetate rayon	1.3–1.5	23–34	100 at 1	25–40
Polyester	4.4–7.8	10–25	100 at 2	50–80
Polypropylene	4.0–7.0	15–25	95 at 7	15–50
Polytetrafluoroethylene	1.7	13	....	

*From Kaswell, "Wellington Sears Handbook of Industrial Textiles," Wellington Sears Co., Inc.

†From Kaswell, "Textile Fibers, Yarns, and Fabrics." Reinhold.

BROOKSTEIN DECLARATION
EXHIBIT 11

United States Patent [19]

Kavesh et al.

[11] **4,413,110**

[45] **Nov. 1, 1983**

[54] **HIGH TENACITY, HIGH MODULUS POLYETHYLENE AND POLYPROPYLENE FIBERS AND INTERMEDIATES THEREFORE**

[75] Inventors: **Sheldon Kavesh**, Whippany; **Dusan C. Prevorsek**, Morristown, both of N.J.

[73] Assignee: **Allied Corporation**, Morris Township, Morris County, N.J.

[21] Appl. No.: **359,019**

[22] Filed: **Mar. 19, 1982**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 259,266, Apr. 30, 1981, abandoned.

[51] **Int. Cl.**^{3} **C08F 10/02**; C08F 10/06; D01F 6/04; D01F 6/06

[52] **U.S. Cl.** **526/348.1**; 264/164; 264/205; 264/210.8; 524/108; 524/366; 524/462; 524/464; 524/583; 524/585; 526/351; 526/352

[58] **Field of Search** 526/348.1, 351, 352

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,137,394 1/1979 Meihuizen et al. 528/502

FOREIGN PATENT DOCUMENTS

3004699 8/1980 Fed. Rep. of Germany .
2051667 1/1981 United Kingdom .

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Smith et al., "Ultrahigh-Strength Polyethylene Filaments by Solution Spinning and Hot Drawing", *Polymer Bulletin*, vol. 1, pp. 733-736, (1979).
Cansfield et al., "The Preparation of Ultra-High Modulus Polypropylene Films and Fibres", *Polymer Eng. & Sci.*, vol. 16, No. 11, pp. 721-724, (1976).
Kalb & Pennings, "Hot Drawing of Porous High Molecular Weight Polyethylene", Polymer Bulletin, vol. 1, pp. 879-880, (1979).
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Smith et al., "Ultra-High-Strength Polyethylene . . . ", *J. Mat. Sci.* 15, (1980), 505-514.
Kalb & Pennings, "Hot Drawing of Porous High Molecular Weight Polyethylene", Polymer 21, (1), 3-4, (1980).
Smook et al., "Influence of Spinning/Hot Drawing Conditions on the Tensile Strength of Porous High Molecular Weight Polyethylene", *Polymer Bulletin*, vol. 2, pp. 775-783, (1980).

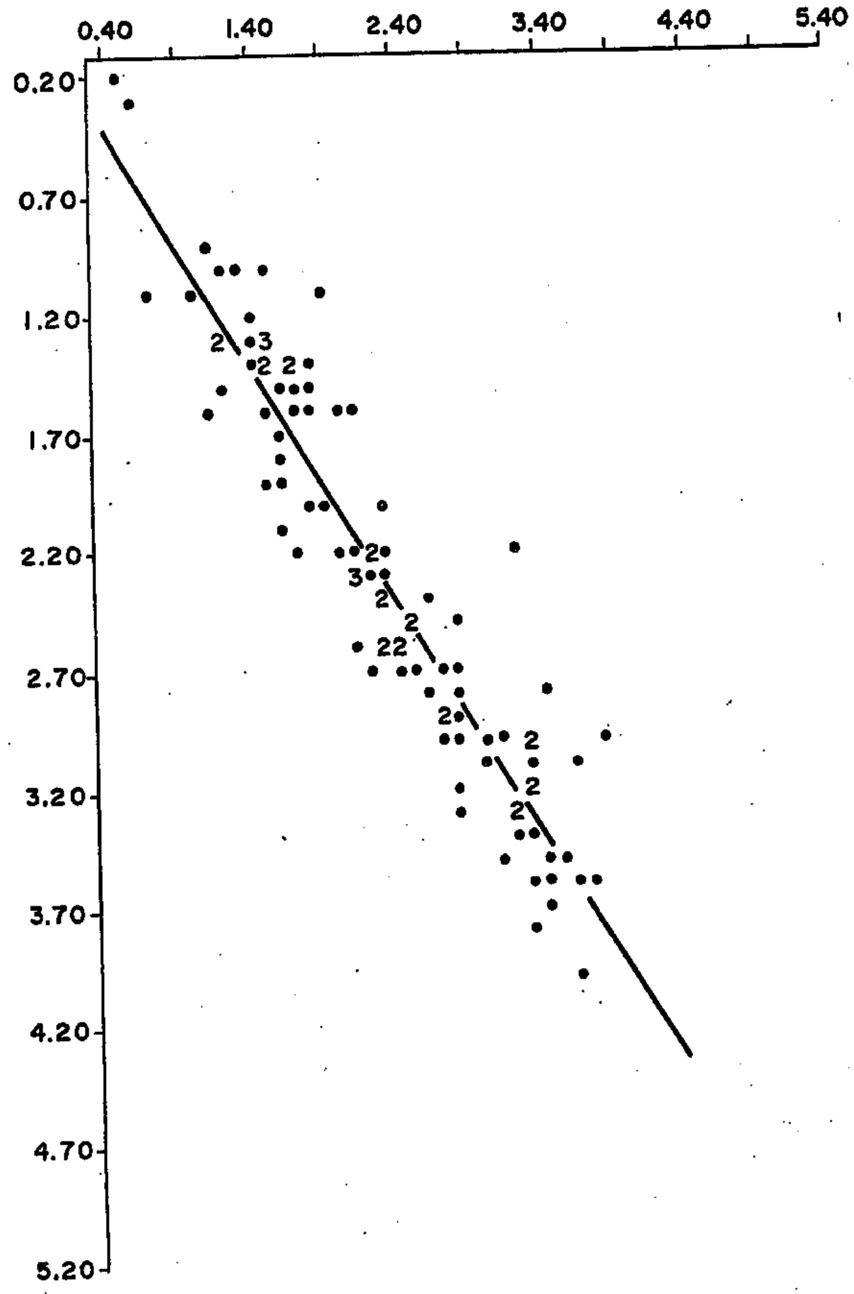
Primary Examiner—Stanford M. Levin
Attorney, Agent, or Firm—Alan M. Doernberg; Gerhard H. Fuchs; Roy H. Massengill

[57] **ABSTRACT**

Solutions of ultrahigh molecular weight polymers such as polyethylene in a relatively non-volatile solvent are extruded through an aperture at constant concentration through the aperture and cooled to form a first gel of indefinite length. The first gels are extracted with a volatile solvent to form a second gel and the second gel is dried to form a low porosity xerogel. The first gel, second gel or xerogel, or a combination, are stretched. Among the products obtainable are polyethylene fibers of greater than 30 or even 40 g/denier tenacity and of modulus greater than 1000 or even 1600 or 2000 g/denier.

19 Claims, 7 Drawing Figures

FIG. 1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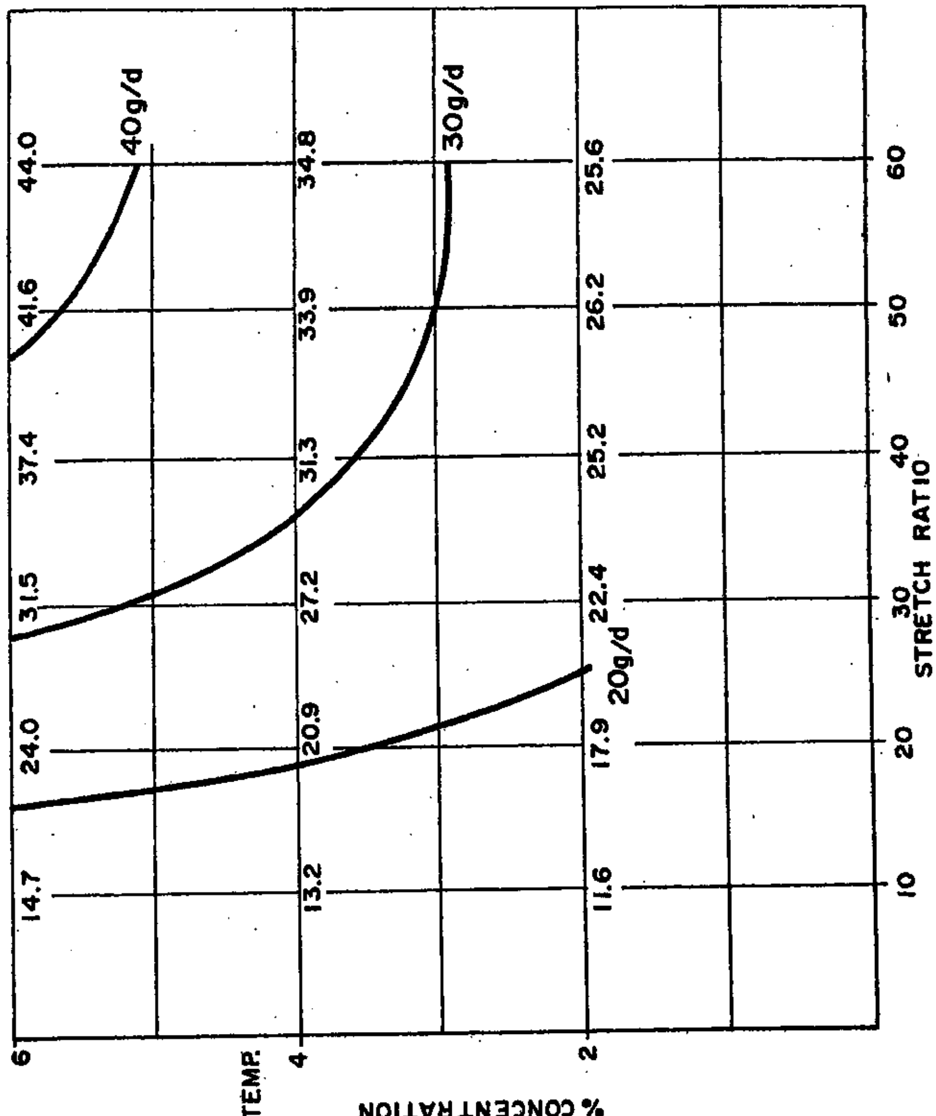


FIG. 2

140°C = STRETCH TEMP.

24 IV PE

FIG. 3

4% GEL CONCENTRATION
24 IV

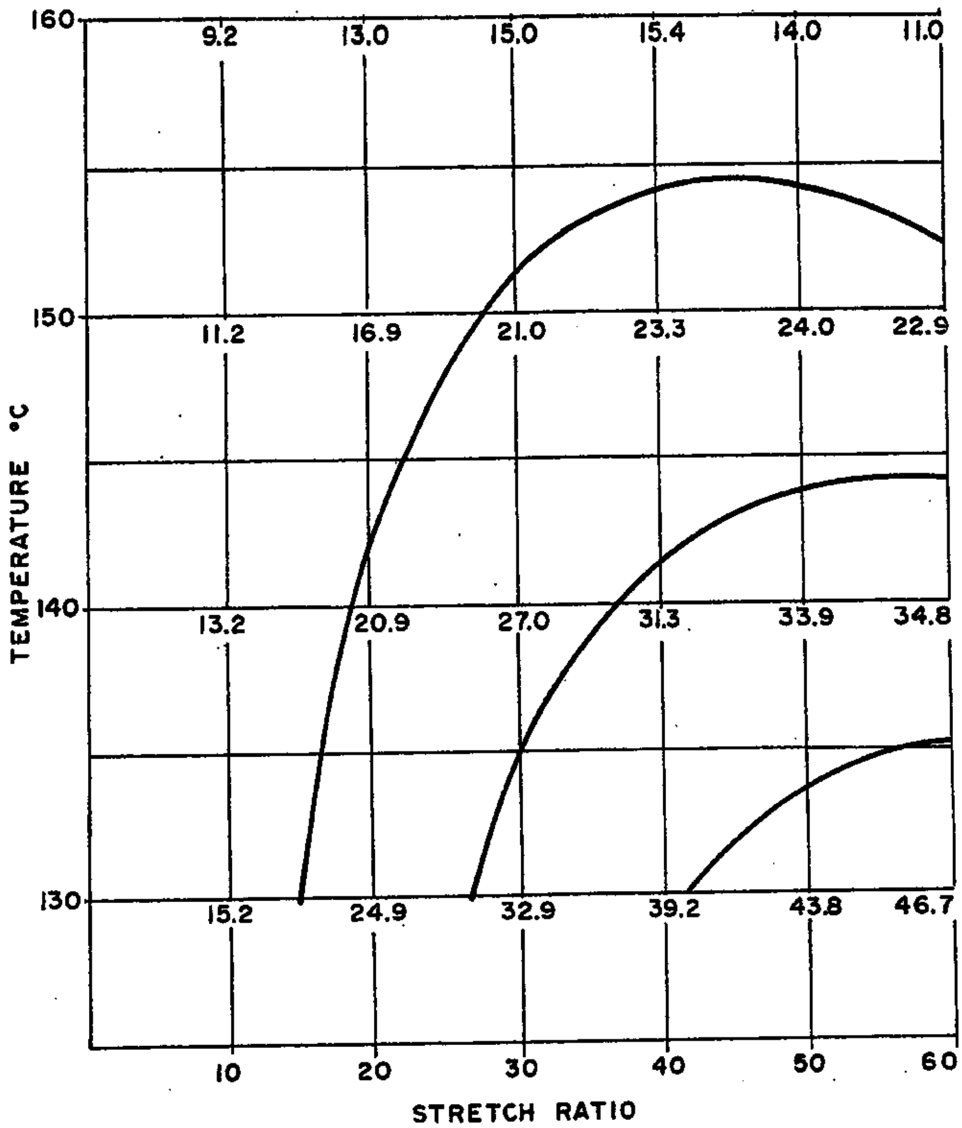
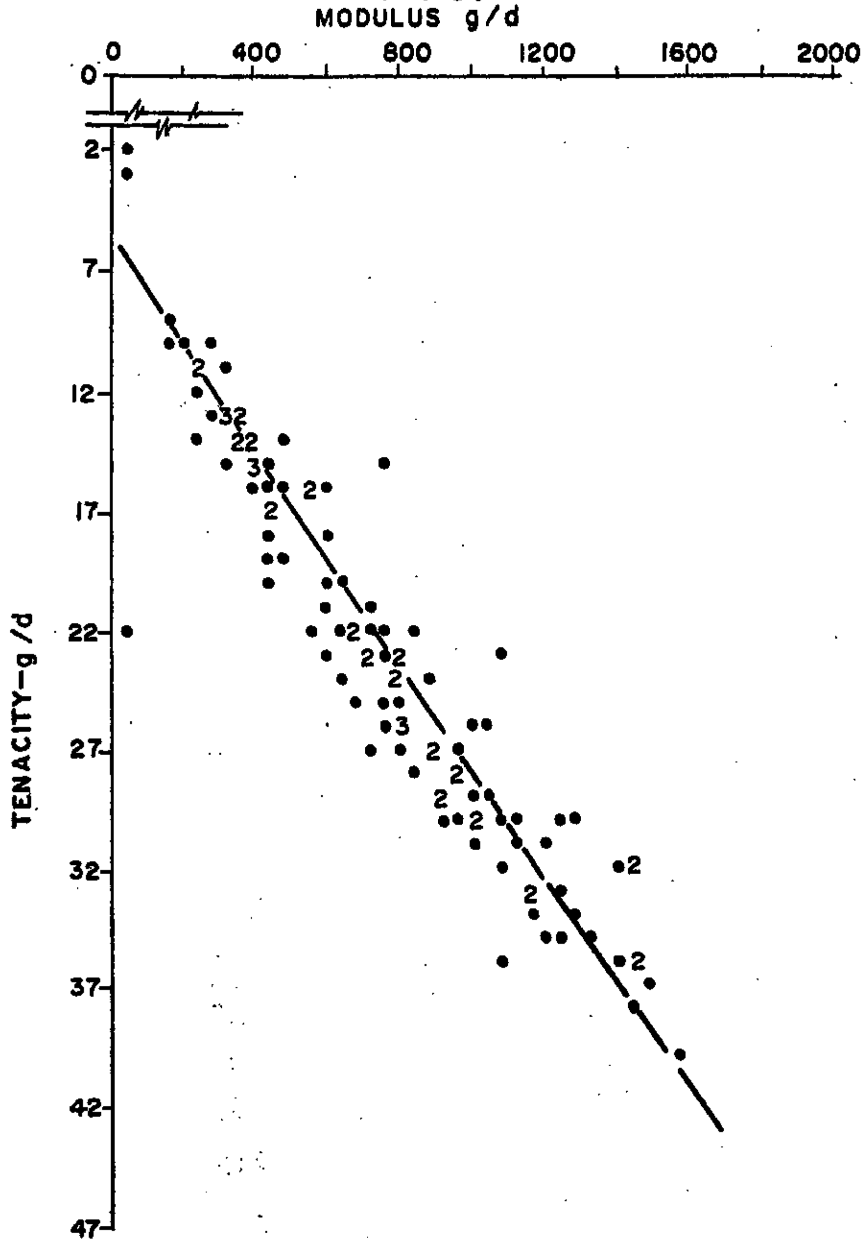


FIG. 4



MODULUS g/d
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TENACITY—g/d
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27
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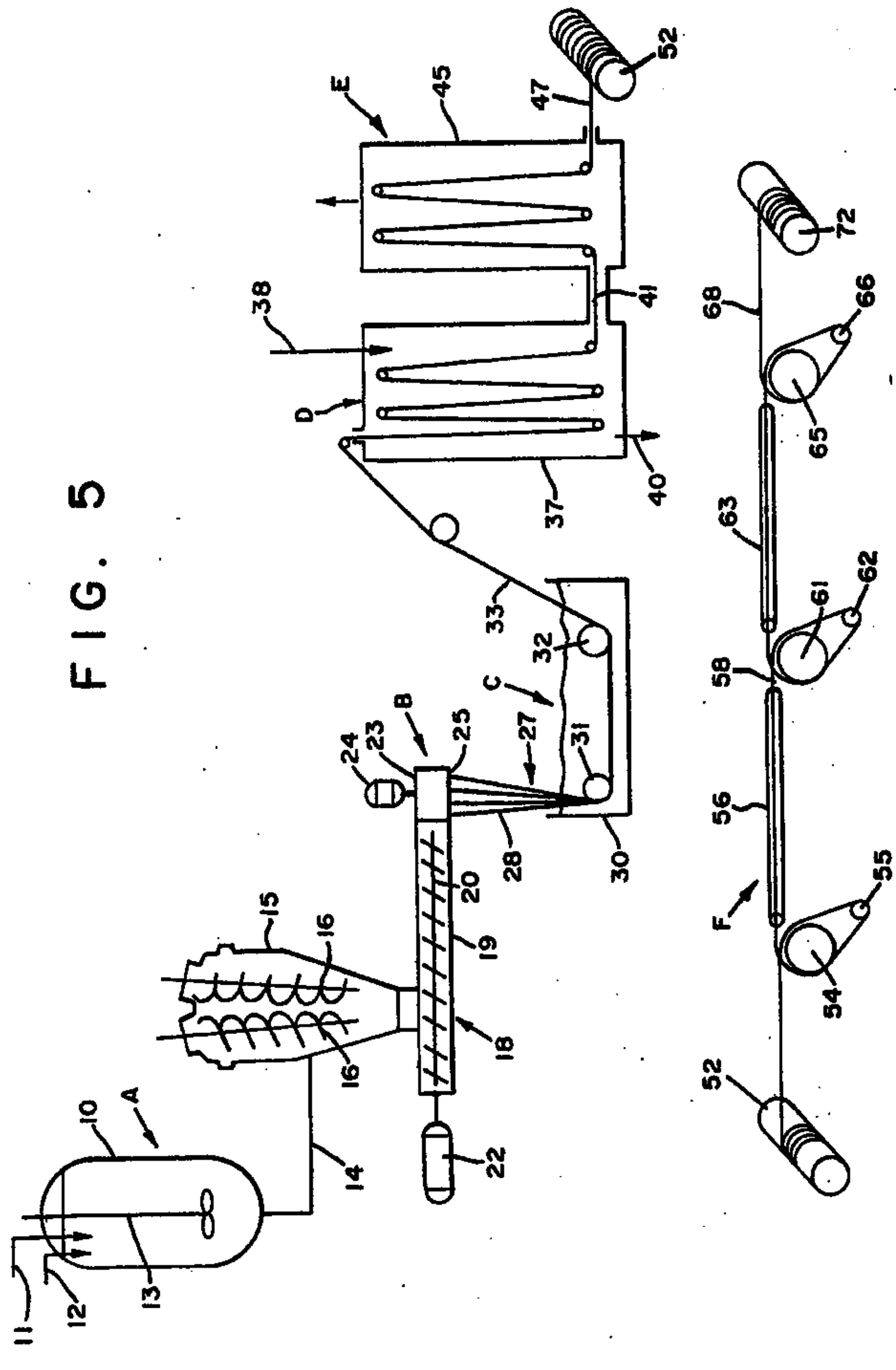
37
42
47

FIG. 5



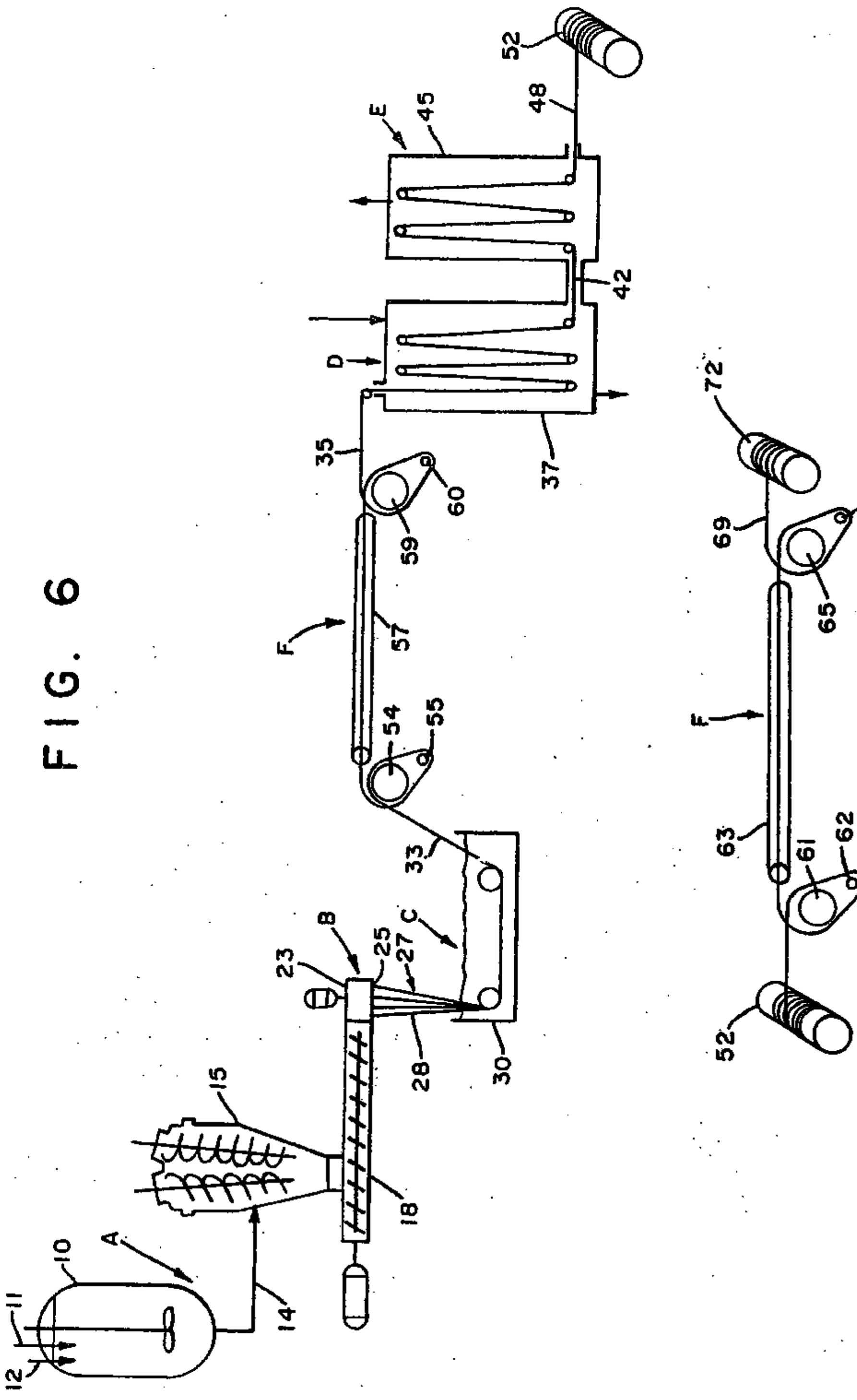


FIG. 6

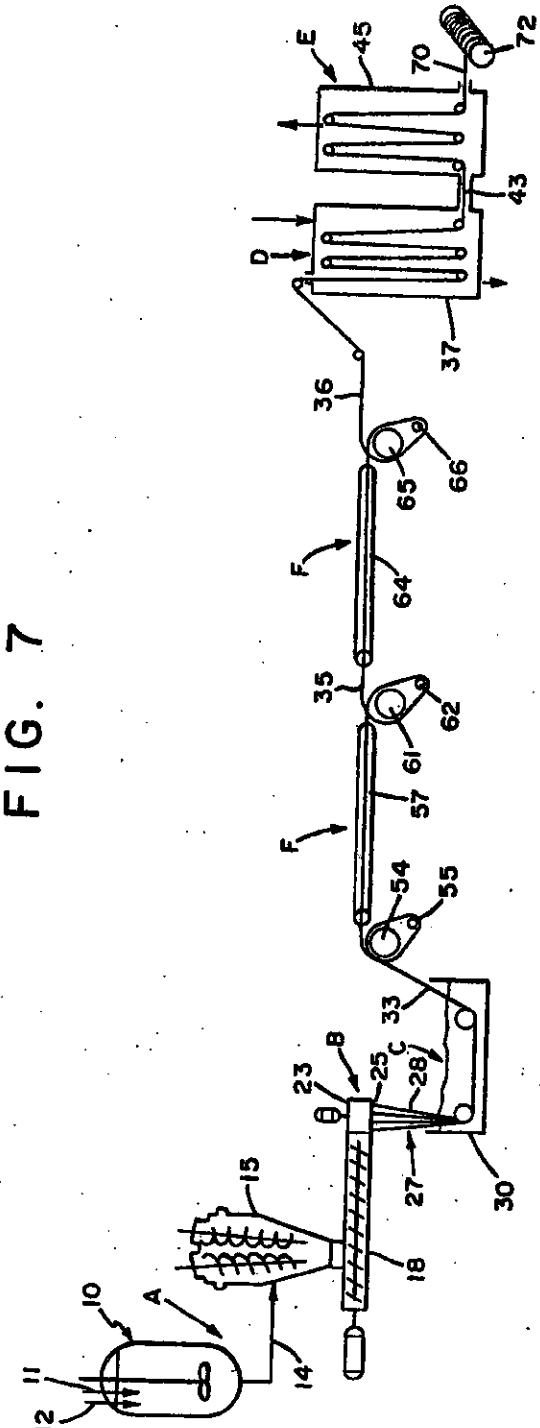


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FIG. 7

HIGH TENACITY, HIGH MODULUS POLYETHYLENE AND POLYPROPYLENE FIBERS AND INTERMEDIATES THEREFORE

DESCRIPTION

This is a continuation-in-part of Ser. No. 259,266, filed Apr. 30, 1981, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to ultrahigh molecular weight polyethylene and polypropylene fibers having high tenacity, modulus and toughness values and a process for their production which includes a gel intermediate.

The preparation of high strength, high modulus polyethylene fibers by growth from dilute solution has been described by U.S. Pat. No. 4,137,394 to Meihuizen et al. (1979) and pending application Ser. No. 225,288 filed Jan. 15, 1981, now U.S. Pat. No. 4,356,138.

Alternative methods to the preparation of high strength fibers have been described in various recent publications of P. Smith, A. J. Pennings and their coworkers. German Off. No. 3004699 to Smith et al. (Aug. 21, 1980) describes a process in which polyethylene is first dissolves in a volatile solvent, the solution is spun and cooled to form a gel filament, and finally the gel filament is simultaneously stretched and dried to form the desired fiber.

UK Patent application GB No. 2,051,667 to P. Smith and P. J. Lemstra (Jan. 21, 1981) discloses a process in which a solution of the polymer is spun and the filaments are drawn at a stretch ratio which is related to the polymer molecular weight, at a drawing temperature such that at the draw ratio used the modulus of the filaments is at least 20 GPa. The application notes that to obtain the high modulus values required, drawing must be performed below the melting point of the polyethylene. The drawing temperature is in general at most 135° C.

Kalb and Pennings in Polymer Bulletin, vol. 1, pp. 879–80 (1979), J. Mat. Sci., vol. 15, 2584–90 (1980) and Smook et at. in Polymer Bull., vol. 2, pp. 775–83 (1980) describe a process in which the polyethylene is dissolved in a nonvolatile solvent (paraffin oil) and the solution is cooled to room temperature to form a gel. The gel is cut into pieces, fed to an extruder and spun into a gel filament. The gel filament is extracted with hexane to remove the paraffin oil, vacuum dried and the stretched to form the desired fiber.

In the process described by Smook et. al. and Kalb and Pennings, the filaments were non-uniform, were of high porosity and could not be stretched continuously to prepare fibers of indefinite length.

BRIEF DESCRIPTION OF THE INVENTION

The present invention includes a stretched polyethylene fiber of substantially indefinite length being of weight avarage molecular weight at least about 500,000 and having a tenacity of at least about 20 g/denier, a tensile modulus at least about 500 g/denier, a creep value no more than about 5% (when measured at 10% of breaking load for 50 days at 23° C.), a porosity less than about 10% and a melting temperature of at least about 147° C. measured at 10° C./minute heating rate by differential scanning calorimetry).

The present invention also includes a stretched polyethylene fiber of substantially indefinite length being of weight average molecular weight of at least about 1,000,000 and having a tensile modulus of at least about 1600 g/denier, a main melting point of at least about 147° C. (measured at 10° C./minute heating rate by differential scanning calorimetry) and an elongation-to-break of not more than 5%.

The present invention also includes a stretched polypropylene fiber of substantially indefinite length being of weight average molecular weight of at least about 750,000 and having a tenacity of at least about 8 g/denier, a tensile modulus of at least about 160 g/denier and a main melting temperature of at least about 168° C. (measured at 10° C./minute heating rate by differential scanning calorimetry)

The present invention also includes a polyolefin gel fiber of substantially indefinite length comprising between about 4 and about 20 weight % solid polyethylene of weight average molecular weight at least about 500,000 or solid polypropylene of weight average molecular weight at least about 750,000, and between about 80 and about 96 weight % of a swelling solvent miscible with high boiling hydrocarbon and having an atmospheric boiling point less than about 50° C.

The preferred method of preparing the novel polyethylene and polypropylene fibers of the present invention is via the novel polyolefin gel fiber of the invention and, more preferably, also via a novel xerogel fiber, by a process claimed in out copending, commonly assigned application Ser. No. 539,020, filed herewith.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graphic view of the tenacities of polyethylene fibers prepared according to Examples 3–99 of the present invention versus calculated values therefore as indicated in the Examples. The numbers indicate multiple points.

FIG. 2 is a graphic view of the calculated tenacities of polyethylene fibers prepared according to Examples 3–99 as a function of polymer concentration and draw ratio at a constant temperature of 140° C.

FIG. 3 is a graphic view of the calculated tenacities of polyethylene fibers prepared according to Examples 3–99 as a function of draw temperature and draw (or stretch) ratio at a constant polymer concentration of 4%.

FIG. 4 is a graphic view of tenacity plotted against tensile modulus for polyethylene fibers prepared in accordance with Examples 3–99.

FIG. 5 is a schematic view of a first process used to prepare the products of the present invention.

FIG. 6 is a schematic view of a second process used to prepare the products of the present invention.

FIG. 7 is a schematic view of a third process used to prepare th products of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

There are many applications which require a load bearing element of high strength, modulus, toughness, dimensional and hydrolytic stability and high resistance to creep under sustained loads.

For example, marine ropes and cables, such as the mooring lines used to secure supertankers to loading stations and the cables used to secure deep sea drilling platforms to underwater anchorage, are presently constructed of materials such as nylon, polyester, aramids and steel which are subject to hydrolytic or corrosive

attack by sea water. In consequence such mooring lines and cables are construted with significant safety factors and are replaced frequently. The greatly increased weight and the need for frequent replacement create substantial operational and economic burdens.

The fibers and films of this invention are of high strength, extraordinarily high modulus and great toughness. They are dimensionally and hydrolytically stable and resistant to creep under sustained loads.

The fibers and films of the invention prepared according to the present process possess these properties in a heretofore unattained combination, and are therefore quite novel and useful materials.

Other applications for the fibers and films of this invention include reinforcements in thermoplastics, thermosetting resins, elastomers and concrete for uses such as pressure vessels, hoses, power transmission belts, sports and automotive equipment, and building construction.

In comparison to the prior art fibers perpared by Smith, Lemstra and Pennings described in Off No. 30 04 699, GB No. 205,1667 and other cited references, the strongest fibers of the present invention are of higher melting point, higher tenacity and much higher modulus. Additionally, they are more uniform, and less porous than the prior art fibers.

In comparison with Off No. 30 04 699 to Smith et. al. the process of the present invention has the advantage of greater controllability and reliability in that the steps of drying and stretching may be separate and each step may be carried out under otimal conditions. To illustrate, Smith & Lemstra in Polymer Bulletin, vol. 1, pp. 733–36 (1979) indicate that drawing temperature, below 143° C., had no effect on the relationships between either tenacity or modulus and stretch ratio. As will be seen, the properties of the fibers of the present invention may be controlled in part by varying stretch temperature with other factors held constant.

In comparison with the procedures described by Smook et. al in Polymer Bulletin, vol. 2, pp. 775–83 (1980) and in the above Kalb and Pennings articles, the process of the present invention has the advantage that the intermediate gel fibers which are spun are of uniform concentration and this concentration is the same as the polymer solution as prepared. The advantages of this unformity are illustrated by the fact that the fibers of the present invention may be stretched in a continuous operation to prepare packages of indefinite length. Additionally, the intermediate xerogel fibers of the present invention preferably contain less than about 10 volume % porosity compared to 23–65% porosity in the dry gel fibers described by Smook et. al. and Kalb and Pennings.

The crystallizable polymer used in the present invention may be polyethylene or polypropylene. In the case of polyethylene, suitable polymers have molecular weights (by intrinsic viscosity) in the range of about one to ten million. This corresponds to a weight average chain length of 3.6×10^4 to 3.6×10^5 monomer units or 7×10^4 to 7.1×10^5 carbons. Polypropylene should have similar backbone carbon chain lengths. The weight average molecular weight of polyethylene used is at least about 500,000 (6 IV), preferably at least about 1,000,000 (10 IV) and morre preferably between about 2,000,000 (16 IV) and about 8,000,000 (42 IV). The weight average molecular weight of polypropylene used is at least about 750,000 (5 IV), preferably at least about 1,000,000 (6 IV), more preferably at least about 1,500,000 (9 IV), and most preferably between about 2,000,000 (11 IV) and about 8,000,000 (33 IV). The IV numbers represent intrinsic visosity of the polymer in decalin at 135° C.

The first solvent should be non-volatile under the processing conditions. This is necessary in order to maintain essentially constant the concentration of solvent upstream and through the aperture (die) and to prevent non-uniformity in liquid content of the gel fiber or film containing first solvent. Preferably, the vapor pressure of the first solvent should be no more than about 20 kPa (about one-fifth of an atmosphere) at 175° C., or at the first temperature. Preferred first solvents for hydrocarbon polymers are aliphatic and aromatic hydrocarbons of the desired non-volatility and solubility for the polymer. The polymer may be present in the first solvent at a first concentration which is selected from a relatively narrow range, e.g. about 2 to 15 weight percent, preferably about 4 to 10 weight percent and more preferably about 5 to 8 weight percent; however, once chosen, the concentration should not vary adjacent the die or otherwise prior to cooling to the second temperature. The concentration should also remain reasonably constant over time (i.e. length of the fiber or film).

The first temperature is chosen to achieve complete dissolution of the polymer in the first solvent. The first temperature is the minimum temperature at any point between where the solution is formed and the die face, and must be greater than the gelation temperature for the polymer in the solvent at the first concentration. For polyethylene in paraffin oil at 5-15% concentration, the gelation temperature is approximately 100–130° C.; therefore, a preferred first temperature can be between 180° C. and 250° C., more preferably 200–240° C. While temperatures may vary above the first temperature at various points upstream of the die face, excessive temperatures causative of polymer degradation should be avoided. To assure complete solubility, a first temperature is chosen whereat the solubility of the polymer exceeds the first concentration, and is typically at least 100% greater. The second temperature is chosen whereas the solubility of the polymer is much less than the first concentration. Preferably, the solubility of the polymer in the first solvent at the second temperature is no more than 1% of the first concentration. Cooling of the extruded polymer solution from the first temperature to the second temperature should be accomplished at a rate sufficiently rapid to form a gel fiber which is of substantially the same polymer concentration as existed in the polymer solution. Preferably the rate at which the extruded polymer solution is cooled from the first temperature to the second temperature should be at least about 50° C. per minute.

Some stretching during cooling to the second temperature is not excluded from the present invention, but the total stretching during this stage should not normally exceed about 2:1, and preferably no more than about 1.5:1. As a result of those factors the gel fiber formed upon cooling to the second temperature consists of a continuous polymeric network highly swollen with solvent. The gel usually has regions of high and low polymer density on a microscopic level but is generally free of large (greater than 500 nm) regions void of solid polymer.

An aperture of circular cross section (or other cross section without a major axis in the plane perpendicular to the flow direction more than 8 times the smallest axis

in the same plane, such as oval, Y- or X-shaped aperature) is used so that both gels will be gel fibers, the xerogel will be an xerogel fiber and the product will be a fiber. The diameter of the aperture is not critical, with representative aperatures being between about 0.25 mm and about 5 mm in diameter (or other major axis). The length of the aperture in the flow direction should normally be at least about 10 times the diameter of the aperture (or other similar major axis), perferably at least 15 times and more preferably at least 20 times the diameter (or other similar major axis).

The extraction with second solvent is conducted in a manner that replaces the first solvent in the gel with second solvent without significant changes in gel structure. Some swelling or shrinkage of the gel may occur, but preferably no substantial dissolution, coagulation or precipitation of the polymer occurs.

When the first solvent is a hydrocarbon, suitable second solvents include hydrocarbons, chlorinated hydrocarbons, chlorofluorinated hydrocarbons and others, such as pentane, hexane, heptane, toluene, methylene chloride, carbon tetrachloride, trichlorotrifluoroethane (TCTFE), diethyl ether and dioxane.

The most preferred second solvents are methylene chloride (B.P. 39.8° C.) and TCFE (B.P. 47.5° C.). Preferred second solvents are the non-flammable volatile solvents having an atmospheric boiling point below about 80° C., more preferably below about 70° C. and most preferably below about 50° C. Conditions of extraction should remove the first solvent to less than 1% of the total solvent in the gel.

A preferred combination of conditions is a first temperature between about 150° C. and about 250° C., a second temperature between about −40° C. and about 40° C. and a cooling rate between the first temperature and the second temperature at least about 50° C./minute. It is preferred that the first solvent be a hydrocarbon, when the polymer is a polyolefin such as ultrahigh molecular weight polyethylene. The first solvent should be substantially non-volatile, one measure of which is that its vapor pressure at the first temperature should be less than one-fifth atmosphere (20 kPa), and more preferably less than 2 kPa.

In choosing the fiirst and second solvents, the primary desired difference relates to volatility as discussed above. It is also preferred that the polymers be less soluble in the second solvent at 40° C. than in the first solvent at 150° C.

Once the gel containing second solvent is formed, it is then dried under conditions where the second solvent is removed leaving the solid network of polymer substantially intact. By analogy to silica gels, the resultant material is called herein a "xerogel" meaning a solid matrix corresponding to the solid matrix of a wet gel, with the liquid replaced by gas (e.g. by an inert gas such as nitrogen or by air). The term "xerogel" is not intended to delineate any particular type of surface area, porosity or pore size.

A comparison of the xerogel fibers of the present invention with corresponding dried gel fibers prepared according to prior art indicates the following major differences in structure: The dried xerogel fibers of the present invention preferably contain less than about ten volume percent pores compared to about 55 volume percent pores in the Kalb and Pennings dried gel fibers and about 23–65 volume percent pores in the Smook et al. dried gel fibers. The dried xerogel fibers of the present invention show a surface area (by the B.E.T. technique) of less than about 1 m^2/g as compared to 28.8 m^2/g in a fiber prepared by the prior art method (see Comparative Example 1 and Example 2, below).

The xerogel fibers of the present invention are also novel compared to dry, unstretched fibers of GB No. 2,051,667 and Off. 3004699 and related articles by Smith and Lemstra. This difference is evidenced by the deleterious effect of stretching below 75° C. or above 135° C. upon the Smith and Lemstra unstretched fibers. In comparison, stretching of the present xerogel fibers at room temperature and above 135° C. has beneficial rather than deleterious effects (see, for example, Examples 540–542, below). While the physical nature of these differences are not clear because of lack of information about Smith and Lemstra's unstretched fibers, it appears that one or more of the following characteristics of the present xerogel fibers must be lacking in Smith and Lemstra's unstretched fibers: (1) a crystalline orientation function less than 0.2, and preferably less than 0.1 as measured by wide angle X-ray diffraction; (2) microporosity less than 10% and preferrably less than 3%; (3) a crystallinity index as measured by wide angle X-ray diffraction (see P. H. Hermans and A. Weidinger, Macromol. Chem. vol. 44, p. 24 (1961)) less than 80% and preferably less than 75% (4) no detectable fraction of the triclinic crystalline form and (5) a fractional variation in spherulite size across a diameter of the fiber less than 0.25.

Stretching may be performed upon the gel fiber after cooling to the second temperature or during or after extraction. Alternatively, stretching of the xerogel fiber may be conducted, or a combination of gel stretch and xerogel stretch may be performed. The stretching may be conducted in a single stage or it may be conducted in two or more stages. The first stage stretching may be conducted at room temperatures or at an elevated temperature. Preferably the stretching is conducted in two or more stages with the last of the stages performed at a temperature between about 120° C. and 160° C. Most preferably the stretching is conducted in at least two stages with the last of the stages performed at a temperature between about 135° C. and 150° C. The Examples, and especially Examples 3–99 and 111–486, illustrate how the stretch ratios can be related to obtaining particular fiber properties.

The product polyethylene fibers produced by the present process represent novel articles in that they include fibers with a unique combination of properties: a tensile modulus at least about 500 g/denier (preferably at least about 1000 g/denier, more preferably at least about 1600 g/denier and most preferably at least about 2000 g/denier), a tenacity at least about 20 g/denier (preferably at least about 30 g/denier and more preferably at least about 40 g/denier), a main melting temperature (measured at 10° C./minute heating rate by differential scanning calorimetry) of at least about 147° C. (preferably at least about 149° C.), a porosity of no more than about 10% (preferably no more than about 6% and more preferably no more than about 3%) and a creep value no more than about 5% (preferably no more than about 3%) when measured at 10% of breaking load for 50 days at 23° C. Preferably the fiber has an elongation to break at most about 7,% and more preferably not more than about 5% (which correlates with the preferred tensile modulus of at least about 1000 g/denier). In addition, the fibers have high toughness and uniformity. Furthermore, as indicated in Examples 3–99 and 111–489 below, trade-offs between various properties

can be made in a controlled fashion with the present process.

The novel polypropylene fibers of the present invention also include a unique combination of properties, previously unachieved for polypropylene fibers: a tenacity of at least about 8 g/denier (preferably at least about 11 g/denier and more preferably at least about 13 g/denier), a tensile modulus at least about 160 g/denier (preferably at least about 200 g/denier and more preferably at least about 220 g/denier), a main melting temperature (measured at 10° C./minute heating rate by differential scanning calorimetry) at least about 168° C. (preferably at least about 170° C.) and a porosity less about 10% (preferably no more than about 5%). Preferably, the polypropylene fibers also have an elongation to break less than about 20%.

Additionally a novel class of fibers of the invention are polypropylene fibers possessing a modulus of at least about 220 g/denier, preferably at least about 250 g/denier.

The gel fibers containing first solvent, gel fibers containing second solvent and xerogel fibers of the present invention also represent novel articles of manufacture, distinguished from somewhat similar products described by Smook et al. and by Kalb and Pennings in having a volume porosities of 10% or less compared to values of 23%-65% in the references.

In particular the second gel fibers differ from the comparable prior art materials in having a solvent with an atmospheric boiling point less than about 50° C. As indicated by Examples 100-108, below, the uniformity and cylindrical shape of the xerogel fibers improved progressively as the boiling point of the second solvent declined. As also indicated in Examples 100-108 (see Table III), substantially higher tenacity fibers were produced under equivalent drying and stretching conditions by using trichlorotrifluoroethane (boiling point 47.5° C.) as the second solvent compared to fibers produced by using hexane (boiling point 68.7° C.) as second solvent. The improvement in final fiber is then directly attributable to changes in the second solvent in the second gel fiber. Preferred such second solvents are halogenated hydrocarbons of the proper boiling point such as methylene chloride (dichloromethane) and trichlorotrifluoroethane, with the latter being most preferred.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 5 illustrates in schematic form a first process to produce the novel fibers, wherein the stretching step F is conducted in two stages on the novel xerogel fiber subsequent to drying step E. In FIG. 5, a first mixing vessel 10 is shown, which is fed with an ultra high molecular weight polymer 11 such as polyethylene of weight average molecular weight at least 500,000 and preferably at least 1,000,000, and to which is also fed a first, relatively non-volatile solvent 12 such as paraffin oil. First mixing vessel 10 is equipped with an agitator 13. The residence time of polymer and first solvent in first mixing vessel 10 is sufficient to form a slurry containing some dissolved polymer and some relatively finely divided polymer particles, which slurry is removed in line 14 to an intensive mixing vessel 15. Intensive mixing vessel 15 is equipped with helical agitator blades 16. The residence time and agitator speed in intensive mixing vessel 15 is sufficient to convert the slurry into a solution. It will be appreciated that the

temperature in intensive mixing vessel 15, either because of external heating, heating of the slurry 14, heat generated by the intensive mixing, or a combination of the above is sufficiently high (e.g. 200° C.) to permit the polymer to be completely dissolved in the solvent at the desired concentration (generally between about 6 and about 10 percent polymer, by weight of solution). From the intensive mixing vessel 15, the solution is fed to an extrusion device 18, containing a barrel 19 within which is a screw 20 operated by motor 22 to deliver polymer solution at reasonably high pressure to a gear pump and housing 23 at a controlled flow rate. A motor 24 is provided to drive gear pump 23 and extrude the polymer solution, still hot, through a spinnerette 25 comprising a plurality of apertures, which may be circular, X-shaped, or, oval-shaped, or in any of a variety of shapes having a relatively small major axis in the plane of the spinnerette when it is desired to form fibers, and having a rectangular or other shape with an extended major axis in the plane of the spinnerette when it is desired to form films. The temperature of the solution in the mixing vessel 15, in the extrusion device 18 and a t the spinnerette 25 should all equal or exceed a first temperature (e.g. 200° C.) chosen to exceed the gellation temperature (approximately 100-130 C. for polyethylene in paraffin oil). The temperature may vary (e.g. 220° C., 210° C. and 200° C.) or may be constant (e.g. 220° C.) from the mixing vessel 15 to extrusion device 18 to the spinnerette 25. At all points, however, the concentration of polymer in the solution should be substantially the same. The number of apertures, and thus the number of fibers formed, is not critical, with convenient number of apertures being 16, 120, or 240.

From the spinnerette 25, the polymer solution passes through an air gap 27, optionally enclosed and filled with an inert gas such as nitrogen, and optionally provided with a flow of gas to facilitate cooling. A plurality of gel fibers 28 containing first solvent pass through the air gap 27 and into a quench bath 30, so as to cool the fibers, both in the air gap 27 and in the quench bath 30, to a second temperature at which the solubility of the polymer in the first solvent is relatively low, such that most of the polymer precipitates as a gel material. While some stretching in the air gap 27 is permissible, it is preferably less than about 2:1, and is more preferably much lower. Substantial stretching of the hot gel fibers in air gap 27 is believed highly detrimental to the properties of the ultimate fibers.

It is preferred that the quench liquid in quench bath 30 be water. While the second solvent may be used as the quench fluid (and quench bath 30 may even be integral with solvent extraction device 37 described below), it has been found in limited testing that such a modification impairs fiber properties.

Rollers 31 and 32 in the quench bath 30 operate to feed the fiber through the quench bath, and preferably operate with little or no stretch. In the event that some stretching does occur across rollers 31 and 32, some first solvent exudes out of the fibers and can be collected as a to layer in quench bath 30.

From the quench bath 30, the cool first gel fibers 33 pass to a solvent extraction device 37 where a second solvent, being of relatively low boiling such as trichlorotrfluoroethane, is fed in through line 38. The solvent outflow in line 40 contains second solvent and essentially all of tthe first solvent brought it with the cool gel fibers 33, either dissolved or dispersed in the second solvent. Thus the second gel fibers 41 conducted

out of the solvent extraction device 37 contain substantially only second solvent, and relatively little first solvent. The second gel fibers 41 may have shrunken somewhat compared to the first gel fibers 33, but otherwise contain substantially the same polymer morphology.

In a drying device 45, the second solvent is evaporated from the second gel fibers 41 forming essentially unstretched xerogel fibers 47 which are taken up on spool 52.

From spool 52, or from a plurality of such spools if it is desired to operate the stretching line at a slower feed rate than the take up of spool 52 permits, the fibers are fed over driven fed roll 54 and idler roll 55 into a first heated tube 56, which may be rectangular, cylindrical or other convenient shape. Sufficient heat is applied to the tube 56 to cause the internal temperature to be between about 120 and 140° C. The fibers are stretched at a relatively high draw ratio (e.g. 10:1) so as to form partially stretched fibers 58 taken up by driven roll 61 and idler roll 62. From rolls 61 and 62, the fibers are taken through a second heated tube 63, heated so as to be at somewhat higher temperature, e.g. 130–160° C. and are then taken up by driven take-up roll 65 and idler roll 66, operating at a speed suficient to impart a stretch ratio in heated tube 63 as desired, e.g. about 2.5:1. The twice stretched fibers 68 produced in this first embodiment are taken up on take-up spool 72.

With reference to the six process steps of the process, it can be seen that the solution forming step A is conducted in mixers 13 and 15. The extruding step B is conducted with device 18 and 23, and especially through spinnerette 25. The cooling step C is conducted in airgap 27 and quench bath 30. Extraction step D is conducted in solvent extraction device 37. The drying step E is conducted in drying device 45. The stretching step F is conducted in elements 52–72, and especially in heated tubes 56 and 63. It will be appreciated, howrever, that various other parts of the system may also perform some stretching, even at temperatures substantially below those of heated tubes 56 and 63. Thus, for example, some stretching (e.g. 2:1) may occur within quench bath 30, within solvent extraction device 37, within drying device 45 or between solvent extraction device 37 and drying device 45.

A second process to produce the novel fiber products is illustrated in schematic form by FIG. 6. The solution forming and extruding steps A and B of the second embodiment are substantially the same as those in the first embodiment illustrated in FIG. 5. Thus, polymer and first solvent are mixed in first mixing vessel 10 and conducted as a slurry in line 14 to intensive mixing device 15 operative to form a hot solution of polymer in first solvent. Extrusion device 18 impells the solution under pressure through the gear pump and housing 23 and then through a plurality of apperatures in spinnerette 27. The hot first gel fibers 28 pass through air gap 27 and quench bath 30 so as to form cool first gel fibers 33.

The cool first gel fibers 33 are conducted over driven roll 54 and idler roll 55 through a heated tube 57 which, in general, is longer than the first heated tube 56 illustrated in FIG. 5. The length of heated tube 57 compensates, in general, for the higher velocity of fibers 33 in the second embodiment of FIG. 6 compared to the velocity of xerogel fibers (47) between take-up spool 52 and heated tube 56 in the first embodiment of FIG. 5. The fibers 33 are drawn through heated tube 57 by driven take-up roll 59 and idler roll 60, so as to cause a relatively high stretch ratio (e.g. 10:1). The once-stretched first gel fibers 35 are conducted into extraction device 37.

In the extraction device 37, the first solvent is extracted out of the gel fibers by second solvent and the novel gel fibers 42 containing second solvent are conducted to a drying device 45. There the second solvent is evaporated from the gel fibers; and novel xerogel fibers 48, being once-stretched, are taken up on spool 52.

Fibers on spool 52 are then taken up by driven feed roll 61 and idler 62 and passed through a heated tube 63, operating at the relatively high temperature of between about 130° and 160° C. The fibers are taken up by driven take up roll 65 and idler roll 66 operating at a speed sufficient to impart a stretch in heated tube 63 as desired, e.g. about 2.5:1. The twice-stretched fibers 69 produced in the second embodiment are then taken up on spool 72.

It will be appreciated that, by comparing the embodiment of FIG. 6 with the embodiment of FIG. 5, the stretching step F has been divided into two parts, with the first part conducted in heated tube 57 performed on the first gel fibers 33 prior to extraction (D) and drying (E), and the second part conducted in heated tube 63, being conducted on xerogel fibers 48 subsequent to drying (E).

A third process to produce novel fiber products is illustrated in FIG. 7, with the solution forming step A, extrusion step B, and cooling step C being substantially identical to the first embodiment of FIG. 5 and the second embodiment of FIG. 6. Thus, polymer and first solvent are mixed in first mixing vessel 10 and conducted as a slurry in line 14 to intensive mixing device 15 operative to form a hot solution of polymer in first solvent. Extrusion device 18 impells the solution under pressure through the gear pump and housing 23 and then through a plurality of apperatures in spinnerette 27. The hot first gel fibers 28 pass through air gap 27 and quench bath 30 so as to form cool first gel fibers 33.

The cool first gel fibers 33 are conducted over driven roll 54 and idler roll 55 through a heated tube 57 which, in general, is longer than the first heated tube 56 illustrated in FIG. 5. The length of heated tube 57 compensates, in general, for the higher velocity of fibers 33 in the third embodiment of FIG. 7 compared to the velocity of xerogel fibers (47) between takeup spool 52 and heated tube 56 in the first embodiment of FIG. 5. The first gel fibers 33 are now taken up by driven roll 61 and idler roll 62, operative to cause the stretch ratio in heated tube 57 to be as desired, e.g. 10:1.

From rolls 61 and 62, the once-drawn first gel fibers 35 are conducted into modified heated tube 64 and drawn by driven take up roll 65 and idler roll 66. Driven roll 65 is operated sufficiently fast to draw the fibers in heated tube 64 at the desired stretch ratio, e.g. 2.5:1. Because of the relatively high line speed in heated tube 64, required generally to match the speed of once-drawn gel fibers 35 coming off of rolls 61 and 62, heated tube 64 in the third embodiment of FIG. 7 will, in general, be longer than heated tube 63 in either the second embodiment of FIG. 6 or the first embodiment of FIG. 5. While first solvent may exude from the fiber during stretching in heated tubes 57 and 64 (and be collected at the exit of each tube), the first solvent is sufficiently non-volatile so as not to evaporate to an appreciable extent in either of these heated tubes.

The twice-stretched first gel fiber 36 is then conducted through solvent extraction device 37, where the second, volatile solvent extracts the first solvent out of the fibers. The second gel fibers, containing substantially only second solvent, is then dried in drying device 45, and the twice-stretched fibers 70 are then taken up on spool 72.

It will be appreciated that, by comparing the third embodiment of FIG. 7 to the first two embodiments of FIGS. 5 and 6, the stretching step (F) is performed in the third embodiment in two stages, both subsequent to cooling step C and prior to solvent extracting step D.

The invention will be further illustrated by the examples below. The first example illustrates the prior art techniques of Smook et. al. and the Kalb and Pennings articles.

COMPARATIVE EXAMPLE 1

A glass vessel equipped with a PTFE paddle stirrer was charged with 5.0 wt% linear polyethylene (sold as Hercules UHMW 1900, having 24 IV and approximately 4×10^6 M.W.), 94.5 wt% paraffin oil (J. T. Baker, 345–355 Saybolt viscosity) and 0.5 wt% antioxidant (sold under the trademark Ionol).

The vessel was sealed under nitrogen pressure and heated with stirring to 150° C. The vessel and its contents were maintained under slow agitation for 48 hours. At the end of this period the solution was cooled to room temperature. The cooled solution separated into two phases-A "mushy" liquid phase consisting of 0.43 wt% polyethylene and a rubbery gel phase consisting of 8.7 wt% polyethylene. The gel phase was collected, cut into pieces and fed into a 2.5 cm (one inch) Sterling extruder equipped with a 21/1 L/D polyethylene-type screw. The extruder was operated at 10 RPM, 170° C. and was equipped with a conical single hole spinning die of 1 cm inlet diameter, 1 mm exit diameter and 6 cm length.

The deformation and compression of the gel by the extruder screw caused exudation of paraffin oil from the gel. This liquid backed up in the extruder barrel and was mostly discharged from the hopper end of the extruder. At the exit end of the extruder a gel fiber of approximately 0.7 mm diameter was collected at the rate of 1.6 m/min. The gel fiber consisted of 24–38 wt% polyethylene. The solids content of the gel fiber varied substantially with time.

The paraffin oil was extracted from the extruded gel fiber using hexane and the fiber was dried under vacuum at 50° C. The dried gel fiber had a density of 0.326 g/cm^3. Therefore, based on a density of 0.960 for the polyethylene constituent, the gel fiber consisted of 73.2 volume percent voids. Measurement of pore volume using a mercury porosimeter showed a pore volume of 2.58 cm^3/g. A B.E.T. measurement of surface area gave a value of 28.8 m^2/g.

The dried fiber was stretched in a nitrogen atmosphere within a hot tube of 1.5 meters length. Fiber feed speed was 2 cm/min. Tube temperature was 100° C. at the inlet increasing to 150° C. at the outlet.

It was found that, because of filament nonuniformity, stretch ratios exceeding 30/1 were not sustainable for periods exceeding about 20 minutes without filament breakage.

The properties of the fiber prepared at 30/1 stretch ratio were as follows:

denier—99
tenacity—23 g/d
modulus—980 g/d
elongation at break—3%
work-to-break—6570 in lbs./in^3 (45 MJ/m^3)

The following example is illustrative of the present invention:

EXAMPLE 2

An oil jacketed double helical (Helicone®) mixer constructed by Atlantic Research Corporation was charged with 5.0 wt% linear polyethylene (Hercules UHMW 1900 having a 17 IV and approximately 2.5×10^6 M.W.) and 94.5 wt% paraffin oil (J. T. Baker, 345–355 Saybolt viscosity). The charge was heated with agitation at 20 rpm to 200° C. under nitrogen pressure over a period of two hours. After reaching 200° C., agitation was maintained for an additional two hours.

The bottom discharge opening of the Helicone mixer was fitted with a single hole capillary spinning die of 2 mm diameter and 9.5 mm length. The temperature of the spinning die was maintained at 200° C.

Nitrogen pressure applied to the mixer and rotation of the blades of the mixer were used to extrude the charge through the spinning die. The extruded uniform solution filament was quenched to a gel state by passage through a water bath located at a distance of 33 cm (13 inches) below the spinning die. The gel filament was wound up continuously on a 15.2 cm (6 inch) diameter bobbin at the rate of 4.5 meters/min.

The bobbins of gel fiber were immersed in trichlorotrifloroethane (fluorocarbon 113 or "TCTFE") to exchange this solvent for paraffin oil as the liquid constituent of the gel. The gel fiber was unwound from a bobbin, and the fluorocarbon solvent evaporated at 22°–50° C.

The dried fiber was of 970±100 denier. The density of the fiber was determined to be 950 kg/m^3 by the density gradient method. Therefore, based on a density of 960 kg/m^3 for the polyethylene constituent, the dried fiber contained one volume percent voids. A B.E.T. measurement of the surface area gave a value less than 1 m^2/g.

The dried gel fiber was fed at 2 cm/min into a hot tube blanketed with nitrogen and maintained at 100° C. at its inlet and 140° C. at its outlet. The fiber was stretched continously 45/1 within the hot tube for a period of three hours without experiencing fiber breakage. The properties of the stretched fiber were:

denier—22.5
tenacity—37.6 g/d
modulus—1460 g/d
elongation—4.1%
work-to-break—12,900 in-lbs/in^3 (89 MJ/m^3)

EXAMPLES 3–99

A series of fiber samples was prepared following the procedures described in Example 2, but with variations introduced in the following material and process parameters:

a. polyethylene IV (molecular weight)
b. polymer gel concentration
c. stretch temperature
d. fiber denier
e. stretch ratio

The results of these experiments upon the final fiber properties obtained are presented in Table I. The Polymer intrinsic viscosity values were 24 in Examples 3–49 and 17 in Examples 50–99. The gel concentration was

2% in Examples 26–41, 4% in Examples 3–17, 5% in Examples 42–99 and 6% in Examples 18–25.

TABLE I

Ex.	Stretch Temp., °C.	Stretch Ratio	Denier	Tenacity g/d	Modulus g/d	Elong %
3	142	15.6	2.8	17.8	455.	6.7
4	145	15.5	2.8	18.6	480.	6.7
5	145	19.6	2.2	19.8	610.	5.2
6	145	13.0	3.4	13.7	350.	6.2
7	145	16.6	2.7	15.2	430.	5.7
8	144	23.9	1.8	23.2	730.	4.9
9	150	16.0	2.7	14.6	420.	5.0
10	150	27.3	1.6	21.6	840.	4.0
11	149	23.8	1.8	21.8	680.	4.6
12	150	27.8	1.6	22.6	730.	4.3
13	140	14.2	3.1	16.5	440.	5.3
14	140	22.0	2.0	21.7	640.	4.7
15	140	25.7	1.7	26.1	810.	4.7
16	140	3.4	5.6	11.2	224.	18.0
17	140	14.9	2.9	20.8	600.	5.6
18	145	19.5	11.7	16.4	480.	6.3
19	145	11.7	19.4	16.3	430.	6.1
20	145	22.3	10.2	24.1	660.	5.7
21	145	47.4	4.8	35.2	1230.	4.3
22	150	15.1	15.0	14.0	397.	6.5
23	150	56.4	4.0	28.2	830.	4.4
24	150	52.8	4.3	36.3	1090	4.5
25	150	12.8	17.8	19.1	440.	7.2
26	143	10.3	21.4	8.7	178.	7.0
27	146	1.8	120.0	2.1	22.	59.7
28	146	3.2	69.5	2.7	37.	40.5
29	145	28.0	7.9	16.0	542.	4.9
30	145	50.2	4.4	21.6	725.	4.0
31	145	30.7	7.2	22.7	812.	4.2
32	145	10.2	21.8	16.2	577.	5.6
33	145	22.3	9.9	15.3	763.	2.8
34	150	28.7	7.7	10.5	230.	8.4
35	150	12.1	18.3	12.6	332.	5.2
36	150	8.7	25.5	10.9	308.	5.9
37	150	17.4	12.7	14.1	471.	4.6
38	140	12.0	18.5	12.7	357.	7.3
39	140	21.5	10.3	16.1	619.	4.2
40	140	36.8	6.0	23.8	875.	4.1
41	140	59.7	3.7	26.2	1031.	3.6
42	145	13.4	25.0	12.9	344.	8.3
43	145	24.4	13.7	22.3	669.	5.9
44	145	25.2	13.3	23.2	792.	4.9
45	145	33.5	10.0	29.5	1005.	4.9
46	150	17.2	19.5	14.2	396.	5.6
47	150	16.0	21.0	15.7	417.	7.2
48	140	11.2	30.0	13.1	316.	8.3
49	140	21.0	16.0	23.0	608.	6.0
50	130	15.8	64.9	14.2	366.	6.0
51	130	44.5	23.1	30.8	1122.	4.4
52	130	24.3	42.4	26.8	880.	4.7
53	130	26.5	38.8	23.6	811.	4.2
54	140	11.0	93.3	14.5	303.	8.4
55	140	28.3	36.3	24.7	695.	4.8
56	140	43.4	23.7	30.3	905.	4.8
57	140	18.4	55.9	19.7	422.	6.6
58	150	15.7	65.5	12.8	337.	8.6
59	150	43.4	23.7	30.9	1210.	4.5
60	150	33.6	30.6	28.9	913.	4.8
61	150	54.4	18.9	30.2	1134.	3.7
62	150	13.6	71.1	10.4	272.	12.2
63	150	62.9	15.4	30.5	1008.	4.0
64	150	26.6	36.4	20.4	638.	7.0
65	150	36.1	26.8	32.0	1081.	5.3
66	150	52.0	18.6	34.0	1172.	4.1
67	150	73.3	13.2	35.3	1314.	3.8
68	140	14.6	66.1	13.9	257.	14.9
69	140	30.1	32.1	28.5	933.	4.5
70	140	45.6	21.2	35.9	1440.	3.9
71	140	43.0	22.5	37.6	1460.	4.1
72	140	32.3	30.1	33.1	1170.	4.3
73	140	57.3	16.9	39.6	1547.	3.8
74	130	16.3	59.4	21.6	556.	5.5
75	130	20.6	47.0	25.6	752.	5.3
76	130	36.3	26.7	33.0	1144.	4.1
77	130	49.4	19.6	30.4	1284.	3.8
78	130	24.5	44.6	26.4	990.	4.5

TABLE I-continued

Ex.	Stretch Temp., °C.	Stretch Ratio	Denier	Tenacity g/d	Modulus g/d	Elong %
79	130	28.6	38.2	27.1	975.	4.5
80	130	42.2	25.9	34.7	1200.	4.4
81	140	40.3	27.1	33.2	1260.	4.0
82	140	58.7	18.6	35.5	1400.	4.0
83	145	47.9	22.8	32.1	1460.	4.0
84	145	52.3	20.9	37.0	1500.	4.0
85	130	13.6	80.4	12.8	275.	8.0
86	130	30.0	36.4	24.8	768.	5.0
87	130	29.7	36.8	28.6	1005.	4.5
88	140	52.0	21.0	36.0	1436.	3.5
89	140	11.8	92.3	10.1	151.	18.5
90	140	35.3	31.0	29.8	1004.	4.5
91	140	23.4	46.8	26.6	730.	5.5
92	150	14.6	74.9	11.5	236.	11.0
93	150	35.7	30.6	27.4	876.	4.5
94	150	31.4	34.8	27.0	815.	5.0
95	150	37.8	28.9	29.8	950.	4.5
96	150	15.9	68.7	9.8	210.	10.0
97	150	30.2	36.2	24.6	799.	5.0
98	150	36.1	30.3	28.2	959.	4.5
99	150	64.7	16.9	32.1	1453.	3.5

In order to determine the relatonships of the fiber properties to the process and material parameters, the data of Table I were subjected to statistical analysis by multiple lnear regression. The regression equation obtained for fiber tenacity was as follows:

$$\text{Tenacity, } g/d = -8.47 + 2.00{*}SR + 0.491{*}IV + 0.0605{*}C{*}SR - 0.00623{*}T{*}SR - 0.0156{*}IV{*}SR - 0.00919{*}SR{*}SR$$

Where

SR is stretch ratio

IV is polymer intrinsic viscosity in decalin at 135° C., dl/g

C is polymer concentration in the gel, wt%

T is stretch temp. °C.

The statistics of the regression were:

F ratio $(6,95)=118$

significance level $=99.9+\%$

standard error of estimate $=3.0$ g/d

A comparison between the observed tenacities and tenacities calculated from the regression equation is shown in FIG. 1.

FIGS. 2 and 3 present response surface contours for tenacity calculated from the regression equation on two important planes.

In the experiments of Examples 3–99, a correlation of modulus with spinning parameters was generally parallel to that of tenacity. A plot of fiber modulus versus tenacity is shown in FIG. 4.

It will be seen from the data, the regression equations and the plots of the calculated and observed results that the method of the invention enables substantial control to obtain desired fiber properties and that greater controlability and flexibility is obtained than by prior art methods.

Further, it should be noted that many of the fibers of these examples showed higher teancities and/or modulus values than had been obtained by prior art methods. In the prior art methods of Off. 30 04 699 and GB 2051667, all fibers prepared had tenacities less than 3.0 GPa (35 g/d) and moduli less than 100 GPa (1181 g/d). In the present instance, fiber examples Nos. 21, 67, 70, 73, 82, 84 and 88 exceeded both of these levels and other fiber examples surpassed on one or the other property.

In the prior art publications of Pennings and coworkers, all fibers (prepared discontinuously) had moduli less than 121 GPa (1372 g/d). In the present instance continuous fiber examples No. 70, 71, 73, 82, 83, 84, 88 and 99 surpassed this level.

The fiber of example 71 was further tested for resistance to creep at 23° C. under a sustained load of 10% of the breaking load. Creep is defined as follows:

$$\%\ \text{Creep} = 100 \times (A(s,t) - B(s))/B(s)$$

where

- B(s) is the length of the test section immediately after application of load
- A(s,t) is the length of the test section at time t after application of load, s
- A and B are both functions of the loads, while A is also a function of time t.

For comparison, a commercial nylon tire cord (6 denier, 9.6 g/d tenacity) and a polyethylene fiber prepared in accordance with Ser. No. 225,288, filed Jan. 15, 1981 by surface growth and subsequent hot stretching (10 denier, 41.5 g/d tenacity) were similarly tested for creep.

The results of these tests are presented in Table II.

TABLE II

CREEP RESISTANCE AT 23° C.
Load: 10% of Breaking Load

Time After Application of Load, Days	% Creep: Fiber of Example 71	% Creep: Comparative Nylon Tire Cord	% Creep: Surface Grown & Stretched Polyethylene
1	0.1	4.4	1.0
2	0.1	4.6	1.2
6	—	4.8	1.7
7	0.4	—	—
9	0.4	—	—
12	—	4.8	2.1
15	0.6	4.8	2.5
19	—	4.8	2.9
21	0.8	—	—
22	—	4.8	3.1
25	0.8	—	—
26	—	4.8	3.6
28	0.9	—	—
32	0.9	—	—
33	—	4.8	4.0
35	1.0	—	—
39	1.4	—	—
40	—	4.9	4.7
43	1.4	—	—
47	1.4	—	—
50	—	4.9	5.5
51	1.4	—	—
57	—	4.9	6.1
59	1.45	—	—

It will be seen that the fiber of example 71 showed about 1.4% creep in 50 days at 23° C. under the sustained load equal to 10% of the breaking load. By way of comparison, both the commercial nylon 6 tire cord and the surface grown polyethylene fiber showed about 5% creep under similar test conditions.

The melting temperatures and the porosities of the fibers of examples 64, 70 and 71 were determined. Melting temperatures were measured using a DuPont 990 differential scanning calorimeter. Samples were heated in an argon atmosphere at the rate of 10° C./min. Additionally, the melting temperature was determined for the starting polyethylene powder from which the fibers of examples 64, 70 and 71 were prepared.

Porosities of the fibers were determined by measurements of their densities using the density gradient technique and comparison with the density of a compression molded plaque prepared from the same initial polyethylene powder. (The density of the compression molded plaque was 960 kg/m³).

Porosity was calculated as follows:

$$\%,\ \text{Porosity} = \frac{960 - \text{fiber density, kg/m}^3}{960}$$

Results were as follows:

Sample	Melting Temp. °C.	Fiber Density, Kg/m³	Porosity, %
Polyethylene powder	138	—	—
Fiber of Example 64	149	982	0
Fiber of Example 70	149	976	0
Fiber of Example 71	150	951	1

The particular level and combination of properties exhibited by the fiber of examples 64, 70 and 71, i.e., tenacity at least about 30 g/d, modulus in excess of 1000 g/d, and creep (at 23° C. and 10% of breaking load) less than 3% in 50 days, melting temperature of at least about 147° C. and porosity less than about 10% appears not to have been attained heretofore.

The following examples illustrate the effect of the second solvent upon fiber properties.

EXAMPLES 100-108

Fiber samples were prepared as described in Example 2, but with the following variations. The bottom discharge opening of the Helicone mixer was adapted to feed the polymer solution first to a gear pump and thence to a single hole conical spinning die. The cross-section of the spinning die tapered uniformly at a 7.5° angle from an entrance diameter of 10 mm to an exit diameter of 1 mm. The gear pump speed was set to deliver 5.84 cm³/min of polymer solution to the die. The extruded solution filament was quenched to a gel state by passage through a water bath located at a distance of 20 cm below the spinning die. The gel filament was wound up continuously on bobbins at the rate of 7.3 meters/min.

The bobbins of gel fiber were immersed in several different solvents at room temperature to exchange with the paraffin oil as the liquid constituent of the gel. The solvents and their boiling points were:

Solvent	Boiling Point, °C.
diethyl ether	34.5
n-pentane	36.1
methylene chloride	39.8
trichlorotrifluoroethane	47.5
n-hexane	68.7
carbon tetrachloride	76.8
n-heptane	98.4
dioxane	101.4
toluene	110.6

The solvent exchanged gel fibers were air dried at room temperature. Drying of the gel fibers was accompanied in each case by substantial shrinkage of transverse dimensions. Surprisingly, it was observed that the shape and surface texture of the xerogel fibers departed progressively from a smooth cylindrical form in approximate proportion to the boiling point of the second solvent. Thus, the fiber from which diethyl ether had

been dried was substantially cylindrical whereas the fiber from which toluene had been dried was "C" shaped in cross-section.

The xerogel fibers prepared using TCTFE and n-hexane as second solvents were further compared by stretching each at 130° C., incrementally increasing stretch ratio until fiber breakage occurred. The tensile properties of the resulting fibers were determined as shown in Table III.

It will be seen that the xerogel fiber prepared using TCTFE as the second solvent could be stretched continuously to a stretch ratio of 49/1 and whereas the xerogel fiber prepared using n-hexane could be stretched continuously only to a stretch ratio of 33/1. At maximum stretch ratio, the stretched fiber prepared using TCTFE second solvent was of 39.8 g/d tenacity, 1580 g/d modulus. This compares to 32.0 g/d tenacity, 1140 g/d modulus obtained using n-hexane as the second solvent.

TABLE III

Properties of Xerogel Fibers Stretched at 130° C. Feed Speed: 2.0 cm/min.

Example	Second Solvent	Stretch Ratio	Tenacity g/d	Modulus g/d	Elong. %
100	TCTFE	16.0	23.3	740	5.0
101	TCTFE	21.8	29.4	850	4.5
102	TCTFE	32.1	35.9	1240	4.5
103	TCTFE	40.2	37.4	1540	3.9
104	TCTFE	49.3	39.8	1580	4.0
105	n-hexane	24.3	28.4	1080	4.8
106	n-hexane	26.5	29.9	920	5.0
107	n-hexane	32.0	31.9	1130	4.5
108	n-hexane	33.7	32.0	1140	4.5

EXAMPLE 110

Following the procedures of Examples 3-99, an 8 wt% solution of isotactic polypropylene of 12.8 intrinsic viscosity (in decalin at 135° C.), approximately 2.1×10^6 M.W. was prepared in paraffin oil at 200° C. A gel fiber was spun at 6.1 meters/min. The paraffin oil was solvent exchanged with TCTFE and the gel fiber dried at room temperature. The dried fiber was stretched 25/1 at a feed roll speed of 2 cm/min. Stretching was conducted in a continuous manner for one hour at 160° C.

Fiber properties were as follows:

denier—105

tenacity—9.6 g/d

modulus—164 g/d

elongation—11.5%

work-to-break—9280 in lbs/in^3 (64 MJ/m^3)

EXAMPLES 111-486

A series of xerogel fiber samples was prepared as in Example 2 but using a gear pump to control melt flow rate. Variations were introduced in the following material and process parameters:

a. polyethylene IV (molecular weight)
b. polymer gel concentration
c. die exit diameter
d. die included angle (conical orifice)
e. spinning temperature
f. melt flow rate
g. distance to quench
h. gel fiber take-up velocity
i. xerogel fiber denier

Each of the xerogel fiber samples prepared was stretched in a hot tube of 1.5 meter length blanketed

with nitrogen and maintained at 100° C. at the fiber inlet and 140° C. at the fiber outlet. Fiber feed speed into the hot tube was 4 cm/min. (Under these conditions the actual fiber temperature was within 1° C. of the tube temperature at distances beyond 15 cm from the inlet). Each sample was stretched continuously at a series of increasing stretch ratios. The independent variables for these experiments are summarized below:

Polymer Intrinsic Viscosity (dL/g)

11.5—Examples 172-189, 237-241, 251-300, 339-371
15.5—Examples 111-126, 138-140, 167-171, 204-236, 242-243, 372-449, 457-459
17.7—Examples 127-137, 141-166, 190-203, 244-250, 301-338
20.9—Examples 450-456, 467-486

Gel Concentration	
5%	Examples 127-137, 141-149, 167-171, 190-203, 244-260, 274-276, 291-306, 339-371
6%	Examples 111-126, 138-140, 204-236, 242-243, 372-418, 431 α 486
7%	Examples 150-166, 172-189, 237-241, 261-273, 277-290, 307-338

Die Diameter Inches	Millimeters	
0.04	1	Examples 167-171, 237-241, 244-260, 274-276, 282-290, 301-306, 317-338, 366-371 and 460-466
0.08	2	Examples 111-166, 172-236, 242, 243, 261-273, 277-281, 291-300, 307-316, 339-365, 372-459 and 467-486.

Die Angle (Degrees)	
0°	Examples 127-137, 141-149, 261-281, 307-316, 339-365, 419-430
7.5°	Examples 111-126, 138-140, 167-171, 204-243, 251-260, 301-306, 317-338, 372-418, 431-486
15°	Examples 150-166, 172-203, 244-250, 282-300, 366-371

Spinning Temperature	
180° C.	Examples 172-203, 237-241, 301-322, 339-371
200° C.	Examples 111-126, 138-140, 167-171, 204-236, 242-243, 372-486
220° C.	Examples 127-137, 141-166, 244-300, 323-338

Solution Flow Rate (cm^3/min)	
2.92 ± 0.02	Examples 116-122, 135-145, 150-152, 162-166, 172-173, 196-201, 214-222, 237, 240, 242-245, 251-255, 260-265, 277-284, 288-293, 301, 304-306, 310-312, 318-320, 347-360, 368-370, 372, 395-397, 401-407, 412-414, 419-424, 450-459, 467-481
4.37 ± 0.02	Examples 204-208, 230-236, 377-379, 408-411
5.85 ± 0.05	Examples 111-115, 123-134, 146-149, 153-161, 167-171, 180-195, 202-203, 209-213, 223-229, 238-239, 241, 256-259, 266-276, 285-287, 294-300, 302-303, 307-309, 315-317, 321-326, 335-338, 361-367, 371, 373-376, 392-394, 398-400, 415-418, 431-433, 482-486
6.07	Examples 339-346

-continued

8.76	Examples 380-391
8.88	Examples 246-250
11.71 ± 0.03	Examples 434-437, 445-449
17.29	Examples 438-440

Distance to Quench		
Inches	Millimeters	Examples
5.5	140	116-126
6.0	152	127-137, 158-166, 172-173, 183-198, 222-229, 240-243, 246-259, 282-286, 293-296, 301, 302, 323-330, 366-368, 398-407, 419-430
6.5	165	268-273, 277-281
7.7	196	167-171
13.0	330	450-453
14.5	368	377-391
15.0	381	230-236, 408-411, 431-449, 454-456, 467-486
22.5	572	307-312, 339-349
23.6	600	111-115, 138-140
24.0	610	141-157, 174-182, 199-203, 209-221, 244-245, 287-292, 297-300, 303-306, 319-322, 331-338, 372, 392-394, 412-418, 460-466

Under all of the varied conditions, the take-up velocity varied from 90-1621 cm/min, the xerogel fiber denier from 98-1613, the stretch ratio from 5-174, the tenacity from 9-45 g/denier, the tensile modulus from 218-1700 g/denier and the elongation from 2.5-29.4%.

The results of each Example producing a fiber of at least 30 g/denier (2.5 GPa) tenacity or at least 1000 g/denier (85 GPa) modulus are displayed in Table IV.

TABLE IV

	Stretched Fiber Properties				
Example	Xerogel Fiber Denier	Stretch Ratio	Tenacity g/den	Modulus g/den	% Elong
113	1599.	50.	31.	1092.	4.0
114	1599.	57.	34.	1356.	3.6
115	1599.	72.	37.	1490.	3.5
119	1837.	63.	35.	1257.	4.2
122	1289.	37.	32.	988.	4.5
126	440.	41.	31.	1051.	4.5
128	1260.	28.	31.	816.	5.5
130	1260.	33.	33.	981.	4.5
131	1260.	43.	35.	1179.	4.0
132	1260.	40.	37.	1261.	4.5
133	1260.	39.	30.	983.	4.0
134	1260.	53.	36.	1313.	4.0
135	282.	26.	29.	1062.	3.5
136	282.	26.	30.	1034.	3.5
137	282.	37.	30.	1261.	3.5
140	168.	23.	26.	1041.	3.5
145	568.	40.	30.	1157.	4.0
146	231.	21.	32.	763.	4.0
147	231.	23.	36.	1175.	4.2
148	231.	22.	33.	1131.	4.0
149	231.	19.	31.	1090.	4.0
151	273.	31.	28.	1117.	3.5
157	1444.	64.	29.	1182.	3.0
160	408.	35.	30.	1124.	4.0
164	1385.	36.	32.	1210.	4.0
166	1385.	39.	33.	1168.	4.0
168	344.	26.	30.	721.	5.0
169	344.	40.	32.	1188.	4.0
170	344.	26.	30.	1060.	4.0
171	344.	29.	31.	1172.	4.0
179	1017.	68.	29.	1179.	4.0
182	352.	65.	33.	1146.	3.7
189	1958.	44.	27.	1050.	3.5
195	885.	59.	31.	1150.	4.0
201	496.	33.	29.	1082.	4.0
206	846.	37.	31.	955.	4.5
208	846.	63.	35.	1259.	3.5

TABLE IV-continued

	Stretched Fiber Properties				
Example	Xerogel Fiber Denier	Stretch Ratio	Tenacity g/den	Modulus g/den	% Elong
212	368.	55.	39.	1428.	4.5
213	368.	49.	35.	1311.	4.0
220	1200.	81.	34.	1069.	4.0
221	1200.	60.	30.	1001.	4.0
227	1607.	42.	30.	1050.	4.0
228	1607.	47.	30.	1114.	3.5
229	1607.	53.	35.	1216.	4.0
233	1060.	34.	30.	914.	4.5
235	1060.	50.	37.	1279.	4.1
236	1060.	74.	45.	1541.	4.0
245	183.	23.	26.	1014.	4.0
247	247.	16.	30.	1005.	4.5
248	247.	10.	30.	1100.	4.0
249	247.	11.	31.	1132.	4.0
250	247.	19.	37.	1465.	3.8
251	165.	34.	31.	1032.	4.5
252	165.	33.	31.	998.	4.5
254	165.	41.	31.	1116.	4.0
255	165.	40.	29.	1115.	4.0
272	1200.	41.	24.	1122.	3.0
273	1200.	64.	27.	1261.	2.5
274	154.	27.	30.	854.	4.5
275	154.	44.	32.	1063.	4.5
276	154.	38.	30.	1054.	4.0
280	291.	39.	30.	978.	4.0
281	291.	43.	29.	1072.	4.0
284	254.	30.	32.	1099.	4.5
308	985.	27.	30.	900.	4.3
309	985.	34.	35.	1210.	3.8
311	306.	30.	31.	990.	4.4
312	306.	30.	32.	1045.	4.0
314	1234.	45.	37.	1320.	4.0
315	344.	25.	30.	970.	4.0
317	254.	29.	32.	1270.	3.5
320	190.	29.	30.	1060.	4.0
322	307.	25.	29.	1030.	4.0
323	340.	25.	34.	1293.	4.1
324	340.	23.	33.	996.	4.4
325	340.	30.	37.	1241.	4.1
326	340.	35.	39.	1480.	3.7
327	373.	24.	30.	920.	4.5
328	373.	27.	34.	1080.	4.5
329	373.	30.	36.	1349.	4.0
330	373.	35.	37.	1377.	3.9
332	218.	34.	35.	1320.	3.9
333	218.	30.	37.	1364.	4.0
334	218.	30.	31.	1172.	3.9
335	326.	26.	37.	1260.	4.5
336	326.	30.	39.	1387.	4.2
337	326.	42.	42.	1454.	4.0
338	326.	42.	37.	1440.	3.9
339	349.	55.	29.	1330.	3.3
345	349.	31.	29.	1007.	4.5
346	349.	51.	34.	1165.	4.3
357	772.	45.	31.	990.	4.4
358	772.	51.	27.	1356.	3.0
359	772.	58.	32.	1240.	3.7
360	772.	59.	33.	1223.	3.8
364	293.	47.	38.	1407.	4.5
375	1613.	50.	30.	960.	4.1
379	791.	46.	32.	1110.	3.9
382	1056.	68.	34.	1280.	3.7
383	921.	51.	31.	1090.	4.0
386	1057.	89.	34.	1250.	3.8
387	984.	59.	33.	1010.	4.3
394	230.	29.	31.	982.	4.3
400	427.	32.	30.	970.	4.1
405	1585.	39.	33.	1124.	3.6
407	1585.	174.	32.	1040.	4.0
418	1370.	51.	33.	1160.	3.7
419	344.	23.	30.	1170.	3.8
421	1193.	30.	31.	880.	4.6
422	1193.	39.	35.	1220.	3.9
423	1193.	51.	34.	1310.	3.4
424	1193.	50.	36.	1390.	3.6
426	1315.	32.	30.	860.	4.4
427	1315.	42.	33.	1160.	3.9

TABLE IV-continued

	Stretched Fiber Properties				
Example	Xerogel Fiber Denier	Stretch Ratio	Tenacity g/den	Modulus g/den	% Elong
428	1315.	46.	34.	1170.	3.8
429	395.	19.	35.	840.	4.5
430	395.	25.	31.	1100.	3.9
435	1455.	36.	31.	920.	4.3
436	1455.	43.	31.	1120.	3.6
437	1455.	51.	33.	1060.	3.3
440	1316.	37.	32.	1130.	4.0
441	453.	31.	32.	990.	4.7
442	453.	49.	39.	1320.	4.4
443	453.	34.	33.	1060.	4.4
444	453.	55.	36.	1410.	3.6
446	402.	28.	30.	1107.	4.0
447	402.	22.	30.	870.	5.0
448	402.	34.	36.	1175.	4.3
449	402.	38.	37.	1256.	4.3
451	461.	33.	33.	1070.	4.4
452	461.	38.	35.	1130.	4.1
453	461.	40.	35.	1220.	3.7
454	64.	14.	34.	1080.	4.7
455	64.	17.	35.	1263.	3.4
456	64.	26.	40.	1453.	3.8
460	268.	32.	35.	1220.	4.3
462	268.	29.	34.	1100.	4.2
463	268.	32.	34.	1110.	4.1
464	268.	43.	40.	1390.	3.9
465	420.	53.	41.	1550.	3.7
466	420.	27.	31.	1010.	4.0
467	371.	24.	31.	960.	4.4
468	371.	63.	45.	1560.	3.9
470	1254.	40.	35.	1100.	4.1
471	1254.	43.	37.	1190.	4.0
472	1254.	45.	38.	1320.	4.0
473	1254.	66.	39.	1600.	3.5
474	210.	44.	43.	1700.	3.5
475	210.	21.	34.	1170.	4.0
476	210.	27.	38.	1420.	3.6
479	1227.	50.	34.	1180.	4.1
480	1227.	48.	33.	1140.	4.1
481	1227.	44.	35.	1230.	4.1
483	1294.	29.	31.	1000.	4.3
484	1294.	42.	36.	1350.	3.7
485	340.	26.	32.	1160.	3.8
486	340.	18.	27.	1020.	4.1

In order to determine the relationships of the fiber properties to the process and material parameters, all of the data from Example 111–486, including those Examples listed in Table IV, were subjected to statistical analysis by multiple linear regression. The regression equation obtained for fiber tenacity was as follows:

$$\begin{aligned}
\text{Tenacity, g/d} &= 11.88 + 2.221IV' + 1.147C' + 1.948TM' \\
&+ 0.822Q' - 1.167L' - 2.438DO' + 0.532SR \\
&- 0.726IV'DA' + 1.399IV'TM' + 0.534IV'L' \\
&+ 0.046IV'SR - 0.754C'DA' - 0.391C'Q' - 0.419C'DO' \\
&- 1.327D'TM' + 0.366D'L' - 0.577DA'TM' \\
&- 0.790DA'Q' - 0.034DA'SR - 0.049TM'SR \\
&+ 0.809Q'L' - 0.313Q'DO' - 0.334(IV')^2 \\
&+ 0.115(L')^2 + 0.564(DO')^2 - 0.00237(SR)^2
\end{aligned}$$

where:

IV'=(polymer IV, dL/g—14.4)/3.1

C'=Gel concentration, %—6

TM'=(spinning temp. °C.—200)/20

Q'=(spin flow rate, cc/min—4.38)/1.46

L'=(distance to quench, in—15)/9

DO'=1.4427 log (xerogel fiber denier/500)

SR=stretch ratio (xerogel fiber denier/stretched fiber denier)

DA'=(die angle, °—7.5)/7.5

D'=(die exit diameter, inches—0.06)/0.02

The statistics of the reggression were;

F ratio (26, 346)=69

Significance Level=99.9+%

Standard error of estimate=2.6 g/denier

In the vicinity of the center of the experimental space these effects may be summarized by considering the magnitude of change in the factor which is required to increase tenacity of 1 g/d. This is given below.

Factor	Factor Change Required to Increase Tenacity By 1 g/denier	
IV	+1	dL/g
Conc.	+1	wt %
Spin Temp.	+10	°C.
Spin Rate	±(saddle)	cc/min
Die Diam.	−0.010	inches
Die Angle	−2	degrees
Dist. to Quench	−4	inches
Xerogel Fiber Denier	−25	
Stretch Ratio	+2/1	

High fiber tenacity was favored by increasing polymer IV, increasing gel concentration, increasing spinning temperature, decreasing die diameter, decreasing distance to quench, decreasing xerogel fiber diameter, increasing stretch ratio and 0° die angle (straight capillary).

It will be seen that the method of the invention enables substantial control to obtain desired fiber properties and that greater controlability and flexability is obtained than by prior art methods.

In these experiments, the effects of process parameters upon fiber modulus generally paralled the effects of these variables upon tenacity. Fiber modulus was correlated with tenacity as follows

modulus, g/d=42(tenacity, g/d)−258

Significance of the correlation between modulus and tenacity was 99.99+%. Standard error of the estimate of modulus was 107 g/d.

It should be noted that many of the fibers of these examples show higher tenacities and/or higher modulus than had seen obtained by prior art methods.

The densities and porosities of several of the xerogel and stretched fibers were determined.

	Xerogel fiber		Stretched fiber	
Example	Density kg/m^3	% Porosity	Density, kg/m^3	% Porosity
115	934	2.7	—	—
122	958	0.2	0.965	0
126	958	0.2	—	—
182	906	5.6	940	2.1

The porosities of these samples were substantially lower than in the prior art methods cited earlier.

EXAMPLES 487–583

In the following examples of multi-filament spinning and stretching, polymer solutions were prepared as in Example 2. The solutions were spun through a 16 hole spinning die using a gear pump to control solution flow rate. The aperatures of the spinning die were straight capillaries of length-to-diameter ratio of 25/1. Each capillary was preceded by a conical entry region of 60° included angle.

The multi-filament solution yarns were quenched to a gel state by passing through a water bath located at a short distance below the spinning die. The gel yarns were wound up on perforated dye tubes.

EXAMPLES 487–495

ONE STAGE "DRY STRETCHING" OF MULTI-FILAMENT YARN

The wound tubes of gel yarn were extracted with TCTFE in a large Sohxlet apparatus to exchange this solvent for paraffin oil as the liquid constituent of the gel. The gel fiber was unwound from the tubes and the TCTFE solvent was evaporated at room temperature.

The dried xerogel yarns were stretched by passing the yarn over a slow speed feed godet and idler roll through a hot tube blanketed with nitrogen, onto a second godet and idler roller driven at a higher speed. The stretched yarn was collected on a winder.

It was noted that some stretching of the yarn (approximately 2/1) occurred as it departed the feed godet and before it entered the hot tube. The overall stretch ratio, i.e., the ratio of the surface speeds of the godets, is given below.

In examples 487–495, the diameter of each hole of the 16 filament spinning die was 0.040 inch one millimeter) the spinning temperature was 220° C., the stretch temperature (in the hot tube) was 140° C. and the feed roll speed during stretching was 4 cm/min. In examples 487–490 the polymer IV was 17.5 and the gel concentration was 7 weight %. In examples 491–495 the polymer IV was 22.6. The gel concentration was 9 weight % in example 491, 8 weight % in examples 492–493 and 6 weight % in examples 494 and 495. The distance from the die face to the quench bath was 3 inches (7.52 cm) in examples 487, 488, 494 and 495 and 6 inches (15.2 cm) in examples 490–493. The other spinning conditions and the properties of the final yarns were as follows:

Ex. No.	Spin Rate cc/min-fil	Gel Fiber Take-up Speed cc/min	SR	Yarn Properties Denier	Ten g/d	Mod g/d	% Elong
487	1.67	1176	35	41	36	1570	3.3
488	2.86	491	25	136	27	1098	3.7
489	2.02	337	25	132	29	1062	3.6
490	2.02	337	30	126	31	1275	3.5
491	1.98	162	25	151	33	1604	3.0
492	1.94	225	25	227	29	1231	3.3
493	1.94	225	30	143	34	1406	3.3
494	1.99	303	30	129	34	1319	3.4
495	1.99	303	35	112	35	1499	3.2

EXAMPLES 496–501

ONE STAGE "WET STRETCHING" OF MULTI-FILAMENT YARN

The wound gel yarns still containing the paraffin oil were stretched by passing the yarn over a slow speed feed godet and idler roll through a hot tube blanketed with nitrogen onto a second godet and idler roll driven at high speed. It was noted that some stretching of the yarn (approximately 2/1) occurred as it departed the feed godet and before it entered the hot tube. The overall stretch ratio, i.e., the ratio of the surface speeds of the godets is given below. The stretching caused essentially no evaporation of the paraffin oil (the vapor pressure of the paraffin oil is about 0.001 atmospheres at 149° C.). However, about half of the paraffin oil content of the gel yarns was exuded during stretching. The stretched gel yarns were extracted with TCTFE in a Sohxlet apparatus, then unwound and dried at room temperature.

In each of the examples 496–501 the spinning temperatures was 220° C., the gel concentration was 6 weight % the distance from the spinning die to the water quench was 3 inches (7.6 cm).

In examples 496 and 499–501 the diameter of each hole of the spinning die was 0.040 inches (0.1 cm). In examples 497 and 498 the hole diameters were 0.030 inches (0.075 cm). In examples 496 and 494–501 the polymer IV was 17.5. In examples 497 and 498 the polymer IV was 22.6. The other spinning conditions and properties of the final yarns were as follows:

Ex. No.	Spinning Rate cc/min-fil	Gel Fiber Take-up Speed cm/min	Stretch Temp	Stretch Ratio	Denier
496	2.02	313	140	22	206
497	1.00	310	140	12.5	136
498	1.00	310	140	15	94
499	2.02	313	120	20	215
500	2.02	313	120	22.5	192
501	2.02	313	120	20	203

Ex. No.	Tenacity g/d	Modulus g/d	% Elong
496	25	1022	3.7
497	28	1041	3.6
498	32	1389	2.8
499	30	1108	4.5
500	30	1163	4.2
501	27	1008	4.2

EXAMPLES 502–533

In the following examples a comparison is made between alternative two stage modes of stretching the same initial batch of yarn. All stretching was done in a hot tube blanketed with nitrogen.

EXAMPLE 502

GEL YARN PREPARATION

The gel yarn was prepared from a 6 weight % solution of 22.6 IV polyethylene as in example 2. The yarn was spun using a 16 hole×0.030 inch (0.075 cm) die. Spinning temperature was 220° C. Spin rate was 1 cm^3/min-fil. Distance from the die face to the quench bath was 3 inches (7.6 cm). Take-up speed was 308 cm/min. Nine rolls of 16 filament gel yarn was prepared.

EXAMPLES 503–576

"WET-WET" STRETCHING

In this mode the gel yarn containing the paraffin oil was stretched twice. In the first stage, three of the rolls of 16 filament gel yarns described in example 502 above were combined and stretched together to prepare a 48 filament stretched gel yarn. The first stage stretching conditions were: Stretch temperature 120° C., feed speed 35 cm/min, stretch ratio 12/1. A small sample of the first stage stretched gel yarn was at this point extracted with TCTFE, dried and tested for tensile properties. The results are given below as example 503.

The remainder of the first stage stretched gel yarn was restretched at 1 m/min feed speed. Other second stage stretching conditions and physical properties of the stretched yarns are given below.

Ex. No.	2nd Stage Stretch Temp - °C.	2nd Stage Stretch Ratio	Denier	Tenacity g/d
503	—	—	504	22
504	130	1.5	320	28
505	130	1.75	284	29
506	130	2.0	242	33
507	140	1.5	303	31
508	140	1.75	285	32
509	140	2.25	222	31
510	145	1.75	285	31
511	145	2.0	226	32
512	145	2.25	205	31
513	150	1.5	310	28
514	150	1.7	282	28
515	150	2.0	225	33
516	150	2.25	212	31

Ex. No.	Modulus g/d	% Elong	Melting* Temp, °C.
503	614	5.5	147
504	1259	2.9	—
505	1396	2.6	150, 157
506	1423	2.8	—
507	1280	3.1	—
508	1367	3.0	149, 155
509	1577	2.6	—
510	1357	3.0	—
511	1615	2.7	—
512	1583	2.5	151, 156
513	1046	3.0	—
514	1254	2.9	—
515	1436	2.9	—
516	1621	2.6	152, 160

*The unstretched xerogel melted at 138° C.

The density of the fiber of example 515 was determined to be 980 kg/m^3. The density of the fiber was therefore higher than the density of a compression molded plaque and the porosity was essentially zero.

EXAMPLES 517–522

"WET-DRY" STRETCHING

In this mode the gel yarn was stretched once then extracted with TCTFE, dried and stretched again.

In the first stage, three of the rolls of 16 filament gel yarn described in Example 502 were combined and stretched together to prepare a 48 filament stretched gel yarn. The first stage stretching conditions were: stretch temperature 120° C., feed speed 35 cm/min, stretch ratio 12/1.

The first stage stretchd gel yarn was extracted with TCTFE in a Sohxlet apparatus, rewound and air dried at room temperature, then subjected to a second stage of stretching in the dry state at a feed speed of 1 m/min. Other second stage stretching conditions and physical properties of the stretching yarn are given below..

Example	2nd Stage Stretch Temp, °C.	2nd Stage Stretch Ratio	Denier	Ten g/d	Mod g/d	% Elong.	Melt Temp, °C.
517	130	1.25	390	22	1193	3.0	—
518	130	1.5	332	26	1279	2.9	150, 157
519	140	1.5	328	26	1291	3.0	—
520	140	1.75	303	27	1239	2.7	150, 159
521	150	1.75	292	31	1427	3.0	—

-continued

Example	2nd Stage Stretch Temp, °C.	2nd Stage Stretch Ratio	Denier	Ten g/d	Mod g/d	% Elong.	Melt Temp, °C.
522	150	2.0	246	31	1632	2.6	152, 158

EXAMPLES 523–533

"DRY-DRY" STRETCHING

In this mode the gel yarn described in example 502 was extracted with TCTFE, dried, then stretched in two stages. In the first stage, three of the rolls of 16 filament yarn were combined and stretched together to prepare a 48 filament stretched xerogel yarn. The first stage stretching conditions were: stretch temperature 120° C., feed speed 35 cm/min., stretch ratio 10/1. The properties of the first stage stretched xerogel yarn are given as example 523 below. In the second stretch stage the feed speed was 1 m/min. Other second stage stretching conditions and physical properties of the stretched yarns are given below.

Example	Stretch Temp, °C.	SR	Denier	Ten g/d	Mod g/d	% Elong.	Melt Temp, °C.
523	—	—	392	21	564	4.3	146, 153
524	130	1.5	387	24	915	3.1	—
525	130	1.75	325	23	1048	2.4	150, 158
526	140	1.5	306	28	1158	2.9	—
527	140	1.75	311	28	1129	2.9	—
528	140	2.0	286	24	1217	2.3	150, 157
529	150	1.5	366	26	917	3.3	—
530	150	1.75	300	28	1170	3.0	—
531	150	2.0	273	31	1338	3.8	—
532	150	2.25	200	32	1410	2.2	—
533	150	2.5	216	33	1514	2.5	152, 156

The density of the fiber of example 529 was determined to be 940 Kg/m^3. The porosity of the fiber was therefore about 2%.

EXAMPLES 534–542

MULTI-STAGE STRETCHING OF MULTI-FILAMENT YARN

In the following examples a comparison is made between two elevated temperatures stretches and a three stage stretch with the first stage at room temperature. The same initial batch of polymer solution was used in these examples.

EXAMPLE 534

UNSTRETCHED GEL YARN PREPARATION

A 6 weight % solution of 22.6 IV polyethylene yarn was prepared as in example 2. A 16 filament yarn was spun and wound as in example 502.

EXAMPLE 535

PREPARATION OF GEL YARN STRETCHED AT ROOM TEMPERATURE

The unstretched gel yarn prepared as in example 534 was led continuously from a first godet which set the spinning take-up speed to a second godet operating at a surface speed of 616 cm/min. In examples 540–542 only, the as-spun gel fiber was stretched 2/1 at room temperature in-line with spinning. The once stretched gel fiber was wound on tubes.

EXAMPLES 536-542

The 16 filament gel yarns prepared in examples 534 and 535 were stretched twice at elevated temperature. In the first of such operations the gel yarns were fed at 35 cm/min to a hot tube blanketed with nitrogen and maintained at 120° C. In the second stage of elevated temperature stretching the gel yarns were fed at 1 m/min and were stretching at 150° C. Other stretching conditions and yarn properties are given below.

Example	SR RT	SR 120° C.	SR 150° C.	Total SR	Denier	Ten g/den	Mod g/den	Elong
536	—	8.3	2.25	18.7	128	23	1510	2.6
537	—	8.3	2.5	20.8	116	30	1630	3.0
538	—	8.3	2.75	22.8	108	30	1750	2.7
539	—	8.3	3.0	24.9	107	31	1713	2.6
540	2	6.8	2.0	27.2	95	30	1742	2.5
541	2	6.8	2.25	30.6	84	34	1911	2.5
542	2	6.8	2.5	34	75	32	1891	2.2

EXAMPLES 543-551

POLYETHYLENE YARNS OF EXTREME MODULUS

The highest experimental value reported for the modulus of a polyethylene fiber appears to be by P. J. Barham and A. Keller, J. Poly. Sci., Polymer Letters ed. 17, 591 (1979). The measurement 140 GPa (1587 g/d) was made by a dynamic method at 2.5 Hz and 0.06% strain and is expected to be higher than would be a similar measurement made by A.S.T.M. Method D2101 "Tensile Properties of Single Man Made Fibers Taken from Yarns and Tows" or by A.S.T.M. Method D2256 "Breaking Load (Stength) and Elongation of Yarn by the Single Strand Method." The latter methods were used in obtaining the data reported here.

The following examples illustrate the preparation of novel polyethylene yarns of modulus exceeding 1600 g/d and in some cases of modulus exceeding 2000 g/d. Such polyethylene fibers and yarns were heretofore unknown. In the following examples all yarns were made from a 22.6 IV polyethylene, 6 weight % solution prepared as in example 2 and spun in example 502. All yarns were stretched in two stages. The first stage stretch was at a temperature of 120° C. The second stage stretch was at a temperature of 150° C. Several 16 filament yarn ends may have been combined during stretching. Stretching conditions and yarn properties are given below.

Example	Feed-1 cm/min	SR-1	Feed-2 cm/min	SR-2	Fils	Ten g/den	Mod g/den	Elong
			Wet - Wet					
543	25	15	100	2.25	48	39	1843	2.9
544	35	12.5	100	2.5	64	31	1952	2.6
545	35	10.5	100	2.75	48	31	1789	2.4
546	100	6.4	200	2.85	48	27	1662	2.5
			Wet - Dry					
547	25	15	100	2.0	48	36	2109	2.5
548	25	15	100	2.0	48	32	2305	2.5
549	25	15	100	2.0	48	30	2259	2.3
550	25	15	100	1.87	48	35	2030	2.7
551	25	15	100	1.95	16	35	1953	3.0

The yarns of examples 548 and 550 were characterized by differential scanning calorimetry and density measurement. The results, displayed below, indicate two distinct peaks at the melting points indicated, quite unlike the broad single peak at 145.5° C. or less reported by Smith and Lemstra in J. Mat. Sci., vol 15, 505 (1980).

Example	Melt Temp(s)	Density	% Porosity
548	147, 155° C.	977 kg/m^3	0
550	149, 156° C.	981 kg/m^3	0

EXAMPLES 552-558

POLYPROPYLENE YARNS OF EXTREME MODULUS

The highest reported experimental value for the modulus of a polypropylene material (fiber or other form) appears to be by T. Williams, J. Mat. Sci. 8, 59 (1973). Their value on a solid state extruded billet was 16.7 GPa (210 g/d). The following examples illustrate the preparation of novel polypropylene continuous fibers with modulus exceeding 220 g/d and in some cases of modulus exceeding 250 g/d.

In the following examples all fibers were made from an 18 IV polypropylene, 6 weight % solution in paraffin oil prepared as in example 2. In Examples 552-556, the fibers were spun with a single hole conical die of 0.040" (0.1 cm) exit diameter and 7.5% angle. Melt temperature was 220° C. A melt pump was used to control solution flow rate at 2.92 cm^3/min. Distance from the die face to the water quench was 3 inches (7.6 cm). The gel fibers were one stage wet stretched at 25 cm/min feed roll speed into a 1.5 m hot tube blanketed with nitrogen. The stretched fibers were extracted in TCTFE and air dried. Other spinning and stretching conditions as well as fiber properties are given below.

Example	Gel Fiber Take-up Speed	Stretch Temp °C.	SR	Denier	Ten g/d	Mod g/d	Elong
552	432	139	10	33	13.0	298	15.8
553	432	138	10	34	13.0	259	18.3

-continued

Example	Gel Fiber Take-up Speed	Stretch Temp °C.	SR	Denier	Ten g/d	Mod g/d	Elong
554	317	140	5	45	11.2	262	19.9
555	317	140	10	51	11.0	220	19.6
556	317	150	10	61	8.8	220	29.8

The fiber of example 556 determined by differential scanning calorimetry to have a first melting temperature of 170°-171° C. with higher order melting temperatures of 173° C., 179° C. and 185° C. This compares with the 166° C. melting point of the initial polymer. The moduli of these fibers substantially exceed the highest previously reported values.

In Examples 557 and 558, the yarns were spun with a 16 hole×0.040 inch (1 mm) capillary die. The solution temperature was 223° C., and the spinning rate was 2.5 cm^3/min-filament. The distance from the die face to the water quench bath was 3 inches (7.6 cm). Take-up speed was 430 cm/min. The gel yarns were "wet-wet" stretched in two stages. The first stage stretching was at 140° C. at a feed speed of 35 cm/min. The second stage stretching was at a temperature of 169° C., a feed speed of 100 cm/min and a stretch ratio of 1.25/1. Other stretching conditions as well as fiber properties are given below.

Example	SR-1	Denier	Ten g/den	Mod g/den	% Elong.
557	9.5	477	10	368	6.8
558	9.0	405	10	376	5.7

The moduli of these yarns very substantially exceed the highest previously reported values.

We claim:

1. A stretched polyethylene fiber of substantially indefinite length being of weight average molecular weight at least about 500,000 and having a tenacity of at least about 20 g/denier, a tensile modulus at least about 500 g/denier, a creep value no more than about 5% (when measured at 10% of breaking load for 50 days at 23° C.), a porosity less than about 10% and a main melting temperature of at least about 147° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

2. The stretched polyethylene fiber of claim 1 having a tenacity of at least about 30 g/denier and a tensile modulus of at least about 1000 g/denier.

3. The stretched polyethylene fiber of claim 2 having a tensile modulus of at least about 1600 g/denier.

4. The stretched polyethylene fiber of claim 2 having a tensile modulus of at least about 2000 g/denier.

5. The stretched polyethylene fiber of claim 1 or 2 having a main melting temperature at least about 149° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

6. The stretched polyethylene fiber of claim 1 or 2 or 3 or 4 having a main melting temperature of at least about 149° C. (measured at 10°/minute heating rate by differential scanning calorimetry).

7. The stretched polyethylene fiber of claim 1 or 2 or 3 or 4 being of weight average molecular weight of at least about 1,000,000.

8. The stretched polyethylene fiber of claim 1 or 2 or 3 or 4 being of weight average molecular weight between about 2,000,000 and about 8,000,000.

9. A stretched polyethylene fiber of substantially indefinite length being of weight average molecular weight of at least about 1,000,000 and having a tensile modulus of at least about 1600 g/denier, a main melting temperature of at least about 147° C. (measured at 10° C./minute heating rate by differential scanning calorimetry) and an elongation-to-break of not more than 5%.

10. The stretched polyethylene fiber of claim 9 being of weight average molecular weight between about 2,000,000 and about 8,000,000.

11. The stretched polyethylene fiber of claim 9 or 10 having a main melting temperature of at least about 149° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

12. The stretched polyethylene fiber of claim 9 or 10 having a tensile modulus of at least about 2000 g/denier.

13. A stretched polypropylene fiber of substantially indefinite length being of weight average molecular weight of at least about 750,000 and having a tenacity of at least about 8 g/denier, a tensile modulus of at least about 160 g/denier and a main melting temperature of at least about 168° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

14. The stretched polypropylene fiber of claim 13 having a tenacity of at least about 11 g/denier.

15. The stretched polypropylene fiber of claim 13 having a tenacity of at least about 13 g/denier.

16. The stretched polypropylene fiber of claim 13 having a tensile modulus of at least about 200 g/denier.

17. The stretched polypropylene fiber of claim 13 having a tensile modulus of at least about 220 g/denier.

18. The stretched polypropylene fiber of claim 13 or 14 or 15 or 16 or 17 being of weight average molecular weight at least about 1,000,000.

19. The stretched polypropylene fiber of claim 13 or 14 or 15 or 16 or 17 being of weight average molecular weight between about 2,000,000 and about 8,000,000.

* * * * *

BROOKSTEIN DECLARATION
EXHIBIT 12

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and B. Reichstädter
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TEXTILE SCIENCE AND TECHNOLOGY 6

PRODUCTION AND APPLICATIONS OF POLYPROPYLENE TEXTILES

by Oldřich Pajgrt
Bohumil Reichstädter
and František Ševčík
Wool Research Institute, Brno, Czechoslovakia

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pylene/cotton blends the
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Gralinski [39].
that no foreign substance
, that various oils, sizes,

textile finishing aids, antistatic agents and others have been removed. In some cases it suffices to treat the blend in distilled water (removal of water-soluble sizes, salts and soaps), while in some others a solvent extraction, using e.g. diethyl ether, chloroform or petroleum ether, should be used in order to remove oils and greases. In removing a formaldehyde-based resin it is recommended to hydrolyze the fibre blend in a boiling 0.02 N HCl under reflux at the fibre-to-liquor ratio of 1 : 100 for 1 hour. The fibre blend is then rinsed to give a neutral reaction.

2.3.3 *Important physical and mechanical properties of polypropylene fibres*

2.3.3.1 Specific volume, density, covering power, appearance and fineness

Polypropylene fibres made of isotactic polymer have a density in the range of 0.90–0.91 g cm^{-3}; the fibres are therefore lighter than water. They have practically the highest specific volume, thus giving also the highest covering power of all common textile fibres.

Some characteristics in this respect for most commercial textile fibres are compared in Table 6. The cross-sectional area given here has been calculated under the presumption that all the fibres have a 0.11 tex fineness and a circular cross-section.

Table 6 — Specific parameters of fibres

Fibre	Density [g cm^{-3}]	Specific volume [cm^3 g^{-1}]	Cross-sectional area [μm^2 tex^{-1}]	[%]
Polypropylene	0.92	1.09	1087	100
Nylon	1.14	0.88	877	81
Acrylic	1.18	0.85	847	78
Polyester	1.38	0.72	725	67
Wool	1.32	0.76	756	70
Cotton	1.50	0.67	667	65
Viscose rayon	1.52	0.66	658	60

From the table it can be derived that the polypropylene fibre gives better cover than nylon, acrylic and polyester fibres by 19, 22 and 33 %, respectively. And when compared with viscose rayon, this difference reaches as much as 40 % in favour of polypropylene.

In other words, when different fibres of the same covering power and, necessarily, of different fineness are used in making comparable

fabrics, the fabrics in theory are lighter or heavier according to what fibres are constituting them.

To give an example on the cover equivalence, some fibres of the same covering power as a 0.33 tex polypropylene fibre are ranked as follows:

0.42 tex nylon fibre
0.43 tex acrylic fibre
0.46 tex triacetate or polyvinylalcohol fibre
0.50 tex polyester or polyvinylchloride fibre
0.55 tex viscose rayon fibre
0.78 tex polytetrafluoroethylene fibre
0.90 tex glass fibre

It follows from the above comparison that, in theory, a knitted or woven fabric made of glass fibre is about three times heavier than that made of polypropylene fibre provided, of course, that the fabrics are of equal construction in order to be comparable.

The given data can be used as a guide only with simple fibres, monofilaments and tapes; with multifilaments and spun yarns a correction should be taken into account due to the porosity.

Appearance and fineness of polypropylene fibres

Polypropylene fibres are white and can vary from lustrous and semi-translucent to dull and opaque in appearance, depending on the amount of delustrant added to the polymer. They can also be dope-dyed to various shades of high fastness.

The fibres have a waxy-to-soapy handle and a smooth, uniform surface, and are mostly circular in cross-section, though some other cross-sectional shapes are also available. They are produced in the fineness ranging from 0.11 to 2.2 tex.

2.3.3.2 Tensile properties

Polypropylene fibres are produced in different forms, such as staple, monofilament, multifilament and low- and high-denier tows, and are modified to suit a particular textile or technical end-use. From the viewpoint of tensile properties they can be divided into the following three groups:

Fibres with a medium tenacity of 400 – 600 mN tex^{-1}

These are the main fibres produced and used most commonly, both as staple and as filament.

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Fibres with a high tenacity of 900 – 1300 mN tex⁻¹

The fibres are intended for special, technical and military uses and are produced as staple, filament and low-denier tow.

Fibres with a low tenacity of 200 – 300 mN tex⁻¹

Staple fibres of this kind are used to advantage in the production of carpet yarns, bestowing on the yarns a high resiliency at the expense of strength. Nevertheless, the strength of the yarns is still sufficient for the purpose. They are commercially produced under such trade names as Meraklon SR and Meraklon DR.

The loop and knot strengths are lower by some 10 – 20 % than the tensile strength. The moisture regain at 21 °C and 65 % R.H. is below 0.1 % and this is why the fibre tenacity remains practically unaltered even after the fibres have been wetted, boiled or steamed for a long time.

Elongation

On average, the elongation varies according to the fibre form as follows:

- monofilament 15 – 30 %
- multifilament 20 – 80 %
- normal-tenacity staple 20 – 35 %
- low-tenacity staple 70 – 100 %
- Meraklon SR 70 – 90 %
- Meraklon DR 70 – 100 %

Load-elongation curves, obtained under standard conditions, for some fibres are shown in Fig. 24. From it a comparison can be made of some kinds of polypropylene fibres including filament, standard staple (Meraklon S, cotton-type) and low-tenacity staple (Meraklon SR, carpet-type), and other commercially important fibres.

2.3.3.3 Elastic properties

Elastic properties of polypropylene fibres can vary along with other mechanical properties in a wide range of values. They depend on the type of polymer and technological conditions in spinning, drawing and preparation, as well as on the technology of textile processing and, in particular, physical and chemical treatments.

To give an example, the elastic recovery at different elongations for a Vectra polypropylene fibre is mentioned briefly below. Both high- and medium-tenacity types of this fibre show comparable elastic recovery giving

at 5 % elongation 80 % instant recovery and no residual deformation,
at 10 % elongation 95 % elastic recovery and 5 % residual deformation,

at 15 % elongation 90 % elastic recovery and 10 % residual deformation,

at 20 % elongation 17.5 % residual deformation.

The fibre exhibiting a very low tenacity of 200 mN tex^{-1}, produced under special conditions at high temperature, gives at 50 % elongation an instant elastic recovery of 95 % and recovers completely after 5 minutes.

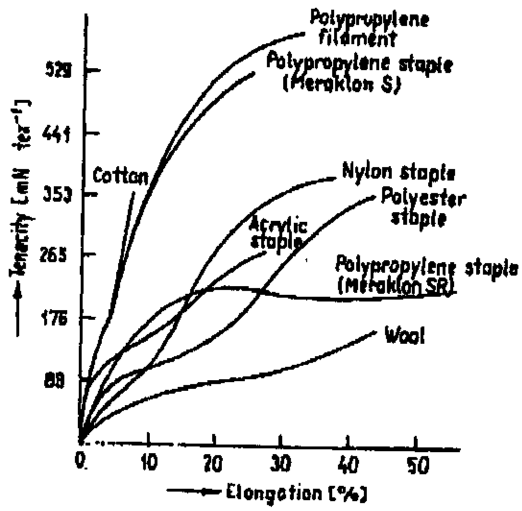

Fig. 24. Load-elongation curves for some fibres

In terms of elasticity polypropylene fibres are ranked below nylons. It should be pointed out that the recovery, and the secondary recovery in particular, of medium-tenacity polypropylene fibres is fairly slow and, in practice, the fibres are considered as only slightly lively.

2.3.3.4 Thermal properties and light exposure

Melting point: about 160 – 175 °C.

Softening point: about 140 – 150 °C.

Heat conductivity: 11.7×10^{-14} J cm^{-1} s^{-1} K^{-1}.

Specific heat: 1.9 J g^{-1} K^{-1}.

Polypropylene fibres show the lowest heat conductivity and, consequently, the highest insulating capacity of all commercial fibres. As for the heat conductivity, given as a relative index against air, some fibres in this respect are compared in Table 7.

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against air, some fibres

Table 7 – Heat conductivity of some textile fibres

Fibre	Index
(Air)	1.0
Polypropylene	2.8
Polyvinylchloride	6.4
Wool	7.4
Acetate	8.6
Viscose rayon	11.0
Cotton	17.5

At −40 °C the fibre preserves its flexibility and shows a higher tenacity and a somewhat lower elongation than at 20 °C. With the increasing temperature the fibre tenacity reduces, as shown in Fig. 25.

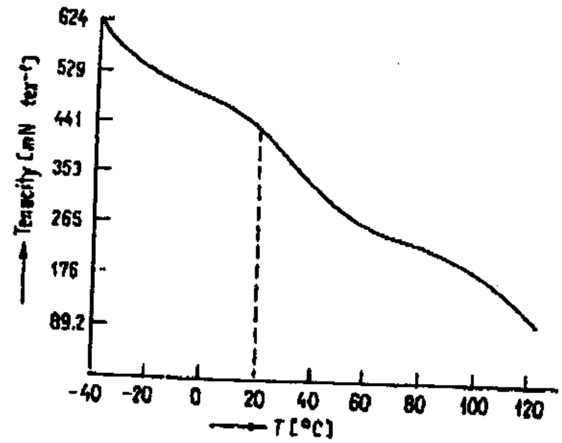

Fig. 25. Effect of temperature on the tenacity of polypropylene fibres

The fibre loses strength gradually with increases in temperature up to the point of softening. At the same time its elongation becomes somewhat higher and the course of the load-elongation relation changes. The zero strength is in the range of 160 – 165 °C. Heat-setting should be effected at about 130 – 135 °C.

Under excessive heat the fibre melts forming a molten droplet. In naked flame it melts and burns, and, detached from the flame, it extinguishes itself or burns only slowly. From the viewpoint of flammability the fibre behaviour is typical of polyolefine fibres.

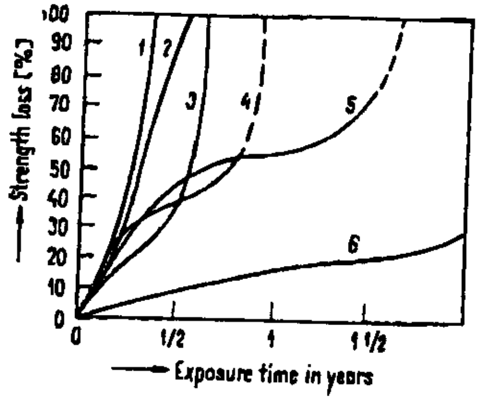

Fig. 26a. Time curves of the resistance of fibres exposed to natural weather conditions for two years in Wilmington in the U.S.A. 1 — silk, 2 — viscose rayon, 3 — acetate, 4 — cotton, 5 — Cordura viscose rayon, 6 — acrylic (Orlon)

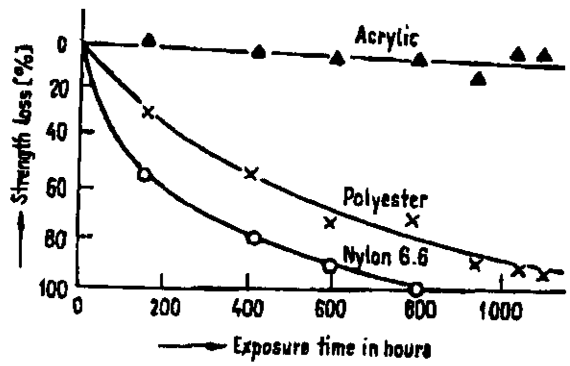

Fig. 26b. Resistance of acrylic, polyester and nylon 6.6 fibres to sunlight

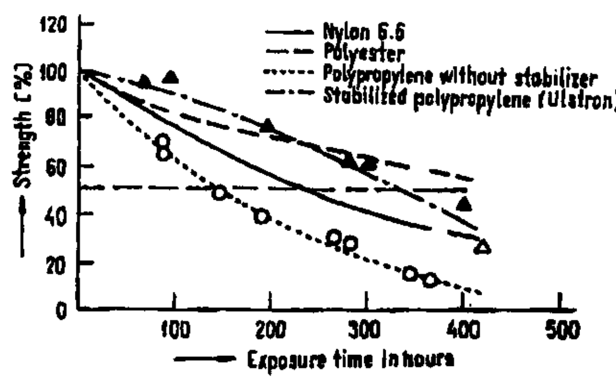

Fig. 26c. Resistance of polyester, nylon 6.6 and polypropylene fibres to weathering in South Florida in the U.S.A.

BROOKSTEIN DECLARATION
EXHIBIT 13

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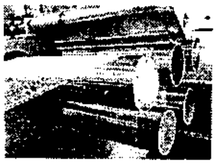

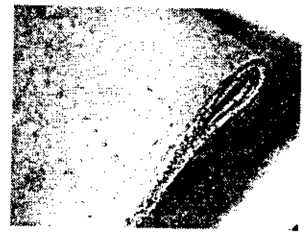

Specialty/High Performance Monofilaments

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- Employment
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PVDF Monofilament: Polyvinylidene Fluoride.

Composition:

- Melt Point = 174°C (345°F)
- Density = 1.78g/cc

Attributes:

- Outstanding resistance to weathering/UV exposure
- Outstanding chemical resistance
- Excellent soil release (low surface energy)
- Low coefficient of friction
- Lowest moisture regain
- High continuous use temperature (150 °C)
- Inherent Flam Resistance

Typical Properties- Trial Lots	MX229
Diameter	0.015
Denier	1850
Tensile Strength (lbs)	19.18
Tenacity (gdp)	4.71
Elongation at Break (%)	17.62
Loop Strength (lbs)	7.19
Loop Tenacity (gdp)	1.76
Loop Elongation (%)	5.5
Loop Impact Strength (ft-lbs/in)	70 (678g wt)
Common Knot Strength (lbs)	8.06
Common Knot Tenacity (gdp)	1.98

Common Knot Elongation (%)	11.4
Free Shrinkage at 132 °C/10 mins (%)	16.3
Boiling Water Shrinkage/5 mins (%)	9.13

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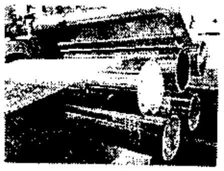

Polyolefin Monofilaments

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- Events
- Documentation
- Products
- Employment
- NEWS

General Characteristics: Generally good chemical resistance. Good biological resistance.

Standard Products	Type	Breaking Strength* GPD	Breaking Strength* KPSI	Shrinkage in boiling water, %
MX-201	PP	4.0	46	11
MX-200	PP	3.0	35	6
MX-305	HDPE	4.2	50	12
MX-306	LDPE	1.7	21	57

PP = Polypropylene

HDPE = High Density Polyethylene

LDPE = Low Density Polyethylene

*GPD - Grams per denier
KPSI = Thousand pounds per square inch

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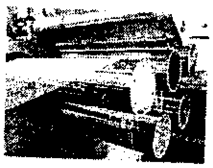
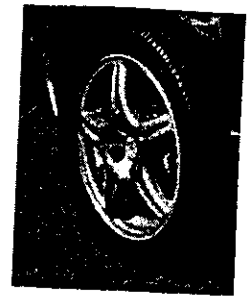
Polyester Monofilaments





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- Sales Organization
- Events
- Documentation
- Products
- Employment
- NEWS

General Characteristics: Dimensionally stable, low moisture regain. Good UV and biological resistance.

Hydrolytically Stabilized Polyester: Specifically formulated to resist degradation caused by hot, moisture environments.

Standard Products	Breaking Strength* GPD	KPSI	Shrinkage at 200 °C, %
WP-550	4.5	80	6.5

Sizes, shapes, colors...

Our monofilaments are available in a wide variety of shapes, colors and sizes depending on polymer types.

Various spool types are also available.

Standard Polyester: For applications not requiring hydrolytic stability.

Standard Products	Breaking Strength* GPD	KPSI	Shrinkage at 200 °C, %
WP-104	4.5	80	3
WP-120	4.5	80	3
WP-200	6.0	107	15
WP-320	6.0	107	20

Superior abrasion resistant products.

*GPD - Grams per denier
KPSI = Thousand pounds per square inch

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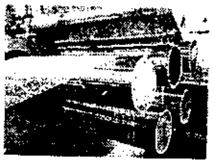

Nylon Monofilaments

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- Sales Organization
- Events
- Documentation
- Products
- Employment
- NEWS

*GPD - Grams per denier
KPSI = Thousand pounds per
square inch

General Characteristics: Tough, abrasion resistant.

Nylon 6: Flexible, resilient, resists compaction.

Standard Products	Breaking Strength* GPD	KPSI	Shrinkage at 175 °C, %
WN-18	6	88	6.5
WN-250	5.5	81	18
NX-1037*	5.5	81	6.5

* Low monomer for wet environments

Nylon 6,10: Low moisture regain. Increased chemical resistance. Improved dimensional stability.

Standard Products	Breaking Strength* GPD	KPSI	Shrinkage at 175 °C, %
WN-50	4.5	63	5
NX-201	5.5	76	12

Nylon 6,6: Higher operating temperature range.

Standard Products	Breaking Strength* GPD	KPSI	Shrinkage at 175 °C, %
WN-101	4.5	66	4
WN-125	5.5	81	3

NX-301	5.0	74	12

Both WN-125 and NX-301 are produced from a heat stabilized, high molecular weight

polymer which increases heat and abrasion.

BROOKSTEIN DECLARATION
EXHIBIT 14

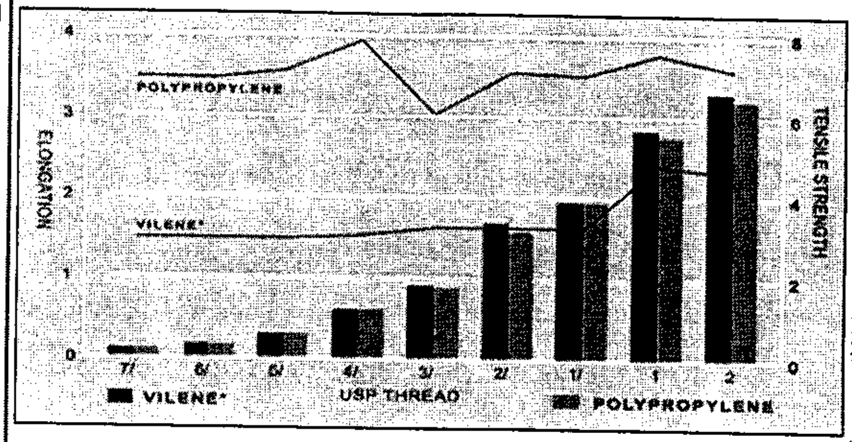
VILENE* - A MONOFILAMENT OF POLYVINYLIDENE FLUORIDE

BACK × HOME

Menu:
Main Pages
Fineline* Cutting
Reverse Cutting
Reverse Premium Cutting
Round Bodied Taper
A-Cute Taper*

◆ MONOFILAMENT P.V.D.F.

VILENE* is a monofilament of Polyvinylidene Fluoride (PVDF) which is non–absorbable physiologically inert. Maintaining it's tensile strength in situ, Vilene provides superior cli to the Surgeon. Combining the high tensile strength and low elongation (see chart belo excellent handling and knotting properties.



NOTES
1. Standard knot pull European Pharmaco US Pharmacopeia V absorbable sutures C for non-sterile suture

2. Standard knot pull a simple knot.

3. Elongation is the e material at break or r pull test expressed a the original length.

Experience has Vilene* has exc security. The springiness that affects all monofilaments when removed from the packag taken out by a gentle pull. It can be used in all procedures where polypropylene monofi utilised. Unlike polypropylene which after sterilisation is waxy in feel and is prone to fra is smooth, fray free and supple. Vilene* is sterilised by gamma irradiation. CV 300 need cardiovascular sutures use a CV300 needle giving the Surgeon optimum performance suture material and needle.

Knotting:
As with all synthetic non-absorbable sutures, knot tying requires the standard surgical t flat and square ties with additional throws as indicated by surgical circumstance.
Vilene is available on the following needles:

- Fineline Cutting
- Reverse Cutting
- Reverse Premium Point Cutting
- Round Bodied Taper
- Round Bodied A-Cute Taper

Both single & double armed sutures are available.

▲TOP

BROOKSTEIN DECLARATION
EXHIBIT 15

FiberWire™

IMPORTANT PRODUCT INFORMATION
WICHTIGE PRODUKTINFORMATION
NOTICE D'UTILISATION IMPORTANTE
IMPORTANTI INFORMAZIONI PER L'USO
INSTRUCCIONES IMPORTANTES PARA EL USO

CE 0086

Arthrex

Manufacturer:
Arthrex Inc.
Naples, Florida 34108-1945 • USA
Toll-Free: +1 800 934-4404
www.arthrex.com

E. C. Representative:
Arthrex Med. Inst. GmbH
85757 Karlsfeld
Germany
Tel: +49 81 31 59 57 0 • Fax: +49 81 31 59 57 63 1

Arthrex

DFU-0065
Rev. 6

Description:
Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (swaged) to the ends in a variety of sizes. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-dyed (white) or dyed and meets or exceeds U.S.P. and European standards (except for diameter).

Indications:
Arthrex FiberWire is indicated for use in soft tissue approximation and or ligation. FiberWire is not for use in cardiac indications.

Actions:
Arthrex FiberWire, when tested per ISO/DIS 10993, *Biological Evaluation of Medical Devices-Part 10: Tests for Irritations and Sensitization*, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength *in vivo*.

Contraindications:
None known

Warnings:
Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Arthrex FiberWire for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:
In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all knots have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

Do not grasp the needle at the point or swage, to avoid damage to these areas. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharps" containers.

Adverse Reactions:
Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:
Arthrex FiberWire suture is supplied sterile.
Method of sterilization - EO
Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

Storage Conditions:
Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:
The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with swaged needles. The Arthrex FiberWire is available in non-dyed (white) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING

Do not reuse
QTY Quantity
STERILE EO Sterile unless the package is damaged or open. Method of sterilization - EO
STERILE R Sterile unless the package is damaged or open. Method of sterilization - gamma radiation
LOT Lot number
See package insert
CE The product meets the essential requirements of Medical Device Directive 93/42 EEC.
Use by - year & month

Beschreibung:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an den Fadenenden befestigten (gesenkgeschmiedeten) Nadeln unterschiedlicher Größen erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe. Arthrex FiberWire ist ungefärbt (weiß) oder gefärbt erhältlich und entspricht oder übertrifft USP- und europäische Standards (mit Ausnahme des Durchmessers).

Anwendungsgebiete:
Arthrex FiberWire ist für Weichgewebeapproximation und/oder -ligation vorgesehen. FiberWire nicht für Kardio-Indikationen verwenden.

Funktionen:
Tests bei Arthrex FiberWire gemäß ISO/DIS 10993, *Biological Evaluation of Medical Devices - Part 10: Reiz- und Sensibilisierungstests* ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nahtmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch unter Umständen vom umgebenden Bindegewebe eingekapselt. Bei Arthrex FiberWire wurde *in vivo* keine signifikante Änderung der Zerreißfestigkeit festgestellt.

Gegenanzeigen:
Unbekannt

Warnhinweise:
Nicht resterilisieren. Unbenutztes Fadenmaterial nach dem Öffnen entsorgen. Von Hitze fernhalten.

Benutzer sollten vor dem Verschließen von Wunden mit Arthrex FiberWire mit den chirurgischen Prozeduren und Techniken vertraut sein, bei denen nicht-absorbierbarer Faden verwendet wird, da das Dehiszenzrisiko je nach Anwendungsstelle und verwendetem Fadenmaterial unterschiedlich ist.

Wie bei Fremdkörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadenmaterials mit Salzlösungen, (wie sie z.B. im Harn- und Gallentrakt vorhanden sind) zu Calculusbildung führen. Bei der Drainage und beim Schließen von infizierten oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorsichtsmaßnahmen:
Bei der Handhabung dieses oder jedes anderen Fadenmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Schäden durch Zusammendrücken oder Abklemmen mit chirurgischen Instrumenten wie Zangen oder Nadelhaltern nach Möglichkeit vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbildungstechniken sicher befestigt wurden. Voraussetzung für angemessene Knotenhaltbarkeit ist die Verwendung von flachen, quadratischen Schleifen mit zusätzlichen Verknotungen, je nach chirurgischer Situation und Erfahrung des Chirurgen. Besonders beim Verknoten von monofilen Fäden sind unter Umständen zusätzliche Verknotungen angebracht. Sorgfältig vorgehen, um Schäden am umgebenden Gewebe und Benutzerpunktierung durch falsche Handhabung der Nadelspitze zu vermeiden.

Die Nadel nicht an der Spitze oder am Gesenk festhalten, um eine Beschädigung dieser Bereiche zu vermeiden. Nadeln können durch Umformen an Stärke verlieren und gegen Verbiegen und Abbrechen weniger widerstandsfähig werden. Nadeln in entsprechend gekennzeichneten Behältern entsorgen.

Nebenwirkungen:
Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Zu den bei nicht-absorbierbarem Faden üblichen Reaktionen zählen unter Umständen Dehiszenz, Calculusbildung in Harn- und Gallenwegen bei längerem Kontakt mit Salzlösungen (wie sie im Urin und in der Gallenflüssigkeit vorhanden sind), verstärkte Bakterieninfektion, minimale akute Gewebeentzündungen, Schmerzen, Ödeme und Erythema an der Wundstelle. Versehentliches Stechen mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Sterilisation:
Arthrex FiberWire wird steril geliefert.
Sterilisationsmethode - EO.
Nicht resterilisieren. Bei beschädigter oder zuvor geöffneter Packung nicht verwenden. Offenes, unbenutztes Fadenmaterial entsorgen.

Lagerungsbedingungen:
Unter 25 °C trocken und fern von direkter Hitzeeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Lieferform:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Das Fadenmaterial wird steril in vorgeschnittenen Längen und in manchen Fällen mit gesenkgeschmiedeten Nadeln geliefert. Arthrex FiberWire ist ungefärbt (weiß) und gefärbt erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE

Nicht wiederverwenden!
QTY Quantität
STERILE EO Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - EO
STERILE R Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - Bestrahlung
LOT Chargenbezeichnung
Siehe Packungsbeilage
CE Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie des Rates über Medizinprodukte 93/42/EWG.
Verwendbar bis Jahr und Monat

Description:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Arthrex FiberWire est également commercialisée avec des aiguilles serties de différentes tailles. Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou teintée, et elle est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Indications:
La suture Arthrex FiberWire est indiquée pour la ligature et le rapprochement des tissus mous. La suture Arthrex FiberWire n'est pas indiquée pour la chirurgie cardiaque.

Réactions:
Aucune réaction allergique ou sensible n'a été observée lors de la soumission de la suture Arthrex FiberWire au test exigé par la norme ISO/DIS 10993 / *Evaluation biologique des dispositifs médicaux, Partie 10 : Essais d'irritation et de sensibilisation*. La suture teintée et le traitement en surface de la suture sont pharmacologiquement inactifs.

La suture Arthrex FiberWire est non résorbable. Elle peut cependant être encapsulée par le tissu conjonctif. Selon les données disponibles, la résistance à la traction de la suture Arthrex FiberWire ne change pas de manière significative *in vivo*.

Contre-indications:
Aucune contre-indication connue.

Précautions d'emploi:
Ne pas stériliser à nouveau. Jeter toute suture non utilisée dont l'emballage a été ouvert. Ne pas exposer à la chaleur.

Tout praticien suturant une plaie avec la suture Arthrex FiberWire doit être familiarisé aux techniques chirurgicales recommandées pour les matériaux non résorbables, car le risque de déhiscence de la plaie varie selon le site de l'intervention et selon le type de suture employé.

Comme avec tout matériau exogène, un contact prolongé de cette suture ou de tout autre fil avec un fluide salin, comme ceux circulant dans les voies urinaires ou biliaires, peut conduire à la formation de calculs. Le praticien devra respecter les règles chirurgicales relatives au drainage et à la fermeture de plaies infectées ou contaminées.

Précautions d'emploi:
Comme avec toute autre suture, éviter d'abîmer le fil lors de sa manipulation. Ne pas écraser le fil avec des instruments chirurgicaux comme une pince ou un porte-aiguille.

Réaliser tous les nœuds conformément aux techniques chirurgicales en vigueur. Opter pour le nœud plat, qui garantit une bonne sécurité et qui est largement utilisé, avec boucles supplémentaires en fonction du cas chirurgical et de l'expérience du praticien. Si le fil est monofilament, prévoir des boucles supplémentaires pour les nœuds.

Bien contrôler la pointe de l'aiguille pour éviter de piquer les tissus environnants ou de blesser le praticien.

Ne pas saisir l'aiguille par sa pointe ou par son attache sur le fil pour éviter de l'endommager. Eviter de modifier la courbure des aiguilles pour ne pas réduire leur résistance à la déformation et à la rupture. Après usage, jeter les aiguilles dans un récipient spécial pour objets pointus et tranchants.

Effets indésirables:
Aucun effet indésirable particulier n'a été observé lors des tests du fil Arthrex FiberWire chez l'animal. Comme avec les autres fils de suture non résorbables, les réactions suivantes sont possibles : déhiscence de la plaie, formation de calculs dans les voies urinaires ou biliaires si contact prolongé avec des fluides salins comme l'urine ou la bile, infectivité bactérienne accrue, inflammation tissulaire minime, douleur, œdème et érythème au niveau de la plaie. Toute blessure avec une aiguille chirurgicale contaminée peut transmettre des germes pathogènes présents dans le sang.

Stérilisation:
La suture Arthrex FiberWire est livrée stérile.
Méthode de stérilisation : oxyde d'éthylène
Ne pas stériliser à nouveau. Ne pas utiliser si l'emballage est ouvert ou endommagé. Jeter les sutures non utilisées si leur emballage est ouvert.

Conditions de stockage:
Conserver à une température maximale de 25°C et à l'abri de l'humidité comme des sources de chaleur directes. Ne pas utiliser après la date d'expiration.

Présentation:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différentes longueurs précoupées. Elle est aussi disponible avec des aiguilles serties. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou en couleurs (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus.

SYMBOLES UTILISÉS SUR L'ÉTIQUETAGE

Ne pas réutiliser | QTY Quantité
STERILE EO Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - EO
STERILE R Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - irradiation
LOT No. de lot | Consulter la notice accompagnant le produit
CE Ce produit est conforme aux exigences de la directive sur les dispositifs médicaux CEE 93/42.
À utiliser avant le (mois/année)

Descrizione:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). FiberWire Arthrex può essere venduto anche con aghi di varie dimensioni attaccati (saldati) alle estremità. La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto. FiberWire Arthrex è disponibile sia non tinto (bianco) che tinto e soddisfa o supera gli standard U.S.P. ed europei (non per diametro).

Indicazioni:
FiberWire Arthrex è indicato per l'approssimazione e/o la legatura dei tessuti molli. FiberWire non va utilizzato in interventi cardiaci.

Azioni:
FiberWire Arthrex, quando testato per ISO/DIS 10993, *Valutazione biologica dei dispositivi medici-Parte 10: I test per irritazioni e sensibilizzazione*, non hanno evidenziato reazioni allergiche o ipersensibilità. La sutura e il rivestimento tinti sono farmacologicamente inattivi.

FiberWire Arthrex non viene assorbito, ma può essere incapsulato nei tessuti connettivi circostanti. Non sono noti per FiberWire Arthrex cambiamenti significativi nella resistenza alla tensione *in-vivo*.

Controindicazioni:
Nessuna nota

Avvertenze:
Non risterilizzare. Una volta aperte, gettare le suture non utilizzate. Non esporre al calore.

Gli utenti devono conoscere bene le procedure e le tecniche chirurgiche relative alle suture non assorbibili prima di utilizzare FiberWire Arthrex per la chiusura delle ferite, in quanto il rischio di deiscenza della ferita può variare in base al sito di applicazione ed al materiale utilizzato per la sutura.

Come per qualsiasi corpo estraneo, il contatto prolungato di questa e qualsiasi altra sutura con soluzioni saline, come quelle presenti nel tratto urinario o biliare, può risultare nella formazione di calcoli. È necessario seguire una pratica chirurgica corretta per il drenaggio e la chiusura di ferite infette o contaminate.

Precauzioni:
Nel trattare questo o qualsiasi altro materiale per sutura, occorre fare attenzione ad evitare danni dovuti al maneggiamento. Evitare danni da schiacciamento o piegature dovuti all'applicazione di strumenti chirurgici, inclusi forcipi o porta-aghi.

Assicurarsi che tutti i nodi siano stati legati usando le tecniche chirurgiche di annodatura accettate. Una sicurezza adeguata del nodo richiede la tecnica chirurgica accettata di legature piatte e quadrate, nonché di ulteriori avvolgimenti in base al caso chirurgico e all'esperienza del chirurgo. L'uso di avvolgimenti aggiuntivi può essere particolarmente appropriato per l'annodamento di monofilamenti. Evitare di recare danni al tessuto circostante o alla puntura dovuti ad una manipolazione non corretta della punta dell'ago.

Non afferrare l'ago per la punta o dalla saldatura, onde evitare danni a queste aree. Il riadattamento degli aghi può indebolirli e renderli meno resistenti alle piegature ed alle rotture. Gettare gli aghi usati in contenitori per materiale «affilato».

Effetti Indesiderati:
Non si sono riscontrati effetti indesiderati con l'uso del prodotto FiberWire Arthrex nei test sugli animali. Le reazioni comuni alle suture non assorbibili possono includere la deiscenza della ferita, la formazione di calcoli nei tratti urinario e biliare dovuta al contatto prolungato con soluzioni saline come urina e bile, infettività batterica elevata, minima reazione del tessuto alle infiammazioni acute, dolore, edema ed eritema al sito della ferita. Il contatto involontario dell'ago con aghi chirurgici contaminati può risultare nella trasmissione di patogeni veicolati dal sangue.

Sterilizzazione:
La sutura FiberWire Arthrex viene fornita sterile.
Metodo di sterilizzazione - EO
Non risterilizzare. Non utilizzare se la confezione è aperta o danneggiata. Gettare le suture aperte non utilizzate.

Condizioni di conservazione:
Conservare al di sotto di 25°C, lontano da umidità e calore diretto. Non utilizzare dopo la data di scadenza.

Come si presenta:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro. La sutura viene fornita sterile in lunghezze pretagliate ed in alcuni casi con aghi saldati. FiberWire Arthrex è disponibile tinto o non tinto (bianco). La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

SIMBOLI USATI SULL'ETICHETTA

Monouso | QTY Quantità
STERILE EO Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - EO
STERILE R Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - Raggi Gamma
LOT Numero di lotto | Fare riferimento all'inserto contenuto nella confezione
CE Il prodotto è conforme ai requisiti essenziali della Direttiva CEE 93/42 sui Dispositivi Medici.
Da usarsi entro anno e mese

Descripción:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas de U.S.P. para suturas, excepto en el diámetro). También es posible encontrar la sutura FiberWire de Arthrex en diversos tamaños y con agujas incorporadas (enhebradas) en los extremos. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido. La sutura FiberWire de Arthrex viene en modelos sin teñir (blanca) o teñida y cumple o supera las normas de U.S.P. y Europa (excepto en el diámetro).

Indicaciones:
La sutura FiberWire de Arthrex está indicada para aplicaciones de aproximación y ligadura de tejido blando. La sutura FiberWire no está indicada para uso cardiaco.

Acciones:
Sutura FiberWire de Arthrex, sometida a prueba de acuerdo con la norma ISO/DIS 10993, *Evaluación Biológica de Dispositivos Médicos-Sección 10: En pruebas para detección de irritaciones y sensibilidad*, no hubo reacciones alérgicas ni de sensibilidad. La sutura teñida y el recubrimiento son inactivos farmacológicamente.

La sutura FiberWire de Arthrex no se absorbe, pero podría encapsularse en los tejidos conjuntivos adyacentes. La sutura FiberWire de Arthrex no presenta cambios significativos conocidos en cuanto a resistencia a la tracción *in vivo*.

Contraindicaciones:
Ninguna conocida

Advertencias:
No esterilizar de nuevo. Una vez abierto el paquete, desechar la sutura no utilizada. No exponer al calor.

Los usuarios deberán conocer los procedimientos quirúrgicos y las técnicas con suturas no absorbibles antes de utilizar FiberWire de Arthrex para cerrar heridas, ya que el riesgo de dehiscencia de las heridas varía según el sitio de aplicación y el material de sutura utilizado.

Al igual que ocurre con todo cuerpo extraño, el contacto prolongado de esta sutura, o de cualquier otro tipo de sutura, con soluciones salinas como las halladas en los tractos urinario o biliar, podría producir cálculos. Se deben usar métodos quirúrgicos aceptables en relación con el drenaje y cierre de heridas infectadas o contaminadas.

Precauciones:
Se debe tener cuidado al manipular esta o cualquier otro material de sutura para evitar dañarlo. No utilice instrumentos quirúrgicos o de aplicación tales como fórceps o porta-agujas para evitar aplastar o plegar el material.

Cerciórese de que todos los nudos se hayan fijado por medio de técnicas aceptadas para nudos quirúrgicos. Para la fijación correcta de los nudos es necesario utilizar la técnica quirúrgica aceptada de nudos planos y cuadrados con lazadas adicionales, según lo requieran las condiciones quirúrgicas y la experiencia del cirujano. El uso de lazadas adicionales podría ser especialmente útil en la elaboración de nudos de monofilamentos. Debe tenerse cuidado para evitar daños al tejido adyacente o punciones producidas por el usuario al manipular incorrectamente la punta de la aguja.

No sujete la aguja por la punta ni por el ojo para evitar daños en esas partes. Si se modifica la forma de las agujas, éstas podrían perder su firmeza y ser menos resistentes a las curvaturas y el rompimiento. Deseche las agujas usadas en recipientes para objetos punzantes.

Reacciones adversas:
No se han detectado reacciones adversas del producto FiberWire de Arthrex en pruebas con animales. Entre las reacciones comunes de las suturas no absorbibles se encuentran: dehiscencia de las heridas, formación de cálculos en los tractos urinario y biliar en condiciones de contacto prolongado con soluciones salinas tales como la orina y la bilis, mayor propensión a infecciones bacterianas, reacción mínima inflamatoria aguda del tejido, dolor, edema y eritema en el sitio de la herida. El pinchazo accidental con agujas quirúrgicas usadas podría causar la transmisión de patógenos a través de la sangre.

Esterilización:
La sutura FiberWire de Arthrex se suministra estéril.
Método de esterilización - EO
No esterilizar de nuevo. No utilizar si el paquete llega abierto o dañado. Desechar las suturas abiertas que no se hayan utilizado.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25° C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en cortes de longitud predeterminada y en algunos casos con agujas enhebradas. La sutura FiberWire de Arthrex se encuentra disponible en modelos sin teñir (blanca) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

SIMBOLOS UTILIZADOS EN LAS ETIQUETAS

No reutilizar | QTY Cantidad
STERILE EO Estéril mientras el envase no sea abierto o dañado. Método de esterilización - EO
STERILE R Estéril mientras el envase no sea abierto o dañado. Método de esterilización - irradiación
LOT Número de lote | Ver folleto en el interior del paquete
CE Este producto cumple con las normas básicas de la Directiva de productos médicos, 93/42 CEE
Caduca - año y mes

BROOKSTEIN DECLARATION
EXHIBIT 16

TO :Arthrex

ATTN: Don Grafton

FROM : Brian Hallett

DATE : 19/10/2000

SUBJECT : <u>Polyester - Dyneema Braid</u>

Dear Don,

Please find enclosed 4 DT trials samples for your inspection ,these have been made using Polyester/Dyneema mixed either in the cover or straight core, to match US2 I have set out below a matrix of how each was made and their results for your information

DT PA23 SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY COVER. STRAIGHT PULL CORE BROKE COVER STAYED INTACT.

16 Carrier m/c
COVER 16 carriers in use each with 1 end of 138 d'tex Polyester per carrier
CORE I end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)
PPI 38

Stage	St/pull kg	Knot/pull kg	Runnage mt/kg	Diameter mm	Extensin %	Solids %
M/c	19.12	9.87	3455	0.677	5.48	
Dye	17.05	8.81		0.589	10	
Stretch	16.51	6.95		0.577	5.3	15.3
Finish	17.2	10.35	3375	0.569	6.8	

DEPUY MITEK
EXHIBIT 164
04cv12457

DT PA25 SAMPLE COMMENTS: BOTH CORE AND COVER BROKE ON THE STRAIGHT PULL AT DYE STAGE, ON THE STRAIGHT PULL AT STRETCH STAGE THE CORE BROKE ONLY
16 Carrier m/c
COVER 16 carriers in use
8 car with 1 end of 113 poly 8 car with 1 end of 110 dyneema
CORE 1 end of 190/1/3 with 10 TPI "S" and 7 TPI "Z"
PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	28.82	11.293	3803	0.582	11.15	
Dye	25.56	10.5		0.582	14.7	
Stretch at 5%	26.84	10.58		0.587	9.9	15.3
Finish	24.35	11.95	3703	0.55	11.2	

DT PA26 SAMPLE COMMENTS: CORE BROKE IN FIRST TWO READINGS ,WHOLE BRAID BROKE IN THIRD
16 Carrier m/c
COVER 16 carriers in use
8 car with 1 end of 113 polyester 8 car with 1 end of 110 Dyneema
CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)
PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	21.82	10.953	3908	0.681	5.28	
Dye	23.62	12.26		0.693	10.1	
Stretch at 5%	24.56	11.79		0.573	5.8	15.3
Finish	21.48	12.87	3786	0.578	6	

DT PA27 SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY COVER, STRAIGHT PULL CORE BROKE COVER STAYED INTACT.
16 Carrier m/c
COVER 16 carriers in use
16 car with 1 end of 113 Polyester per carrier
CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)
PPI 44

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	19.14	9.037	4033	0.549	5.9	
Dye	16.18	8.35		0.548	8.5	
Stretch at 5%	16.49	6.54		0.545	5.5	15.3
Finish	16.12	8.04	3919	0.553	5.6	

If I can be any further assistance please do not hesitate to contact me

Kind regards
Brian Hallett
Brian Hallett
Product Development Manager

BROOKSTEIN DECLARATION
EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

______________________________/

DEPOSITION OF:	ASHLEY HOLLOWAY
DATE:	September 15, 2005
TIME:	1:08 p.m. to 5:07 p.m.
LOCATION:	The Ritz Carlton Golf Resort 2600 Tiburon Drive Naples, FL 34112
TAKEN BY:	Plaintiff
REPORTER:	Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER:	Les Smoak, CLVS

30

suture --
A. Correct.
Q. -- with respect to knot security; is that right?
A. Correct.
Q. Okay. Does Arthrex test its FiberWire sutures for pliability?
A. No.
Q. Do you know what pliability means?
A. Pliability --
Q. As it relates to FiberWire sutures?
A. I don't know the exact definition, no.
Q. But Arthrex does not test its FiberWire sutures for pliability?
A. No.
Q. Has it ever tested its FiberWire sutures for pliability?
A. Not that I'm aware of.
Q. Does Arthrex test its FiberWire sutures for handleability?
A. Yes.
Q. How does Arthrex test its FiberWire sutures for handleability?
A. It's a subjective test.
Q. What do you mean by that?
A. I mean basically we give a piece of suture to a

31

product manager or a surgeon who is familiar with the field of sutures and ask them to give us feedback on the handleability.
Q. And what is handleability measured in?
A. There are no units. It's subjective.
Q. So what does "handleability" mean? What does the definition of "handleability" mean as Arthrex uses that as a test for its FiberWire sutures?
A. What do I think it means?
Q. What does Arthrex think it means?
A. I think handleability as is it easy to move through the tissue or pass through the tissue? Is it easy to slide knots? Is it easy to tie knots?
Q. Anything else?
A. Is it easy to slide through the anchor eyelet?
Q. Anything else?
A. Not that I can think of.
Q. Do materials contribute to the handleability of Arthrex's FiberWire sutures?
MR. TAMBURO: Objection to form.
A. Yes.
MR. TAMBURO: Also, it's outside the scope.
Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
A. All materials used.

32

Q. What do you mean by that?
A. I mean everything that's in that construct.
Q. Contributes to the handleability of the suture?
A. Yes.
Q. What is the handleability of Arthrex's FiberWire suture?
MR. TAMBURO: Objection to form.
A. Do you want me to give you a subjective answer?
Q. Let me rephrase the question. Has Arthrex received feedback from surgeons on the handleability of Arthrex's FiberWire suture?
A. Yes.
Q. And what was the feedback that Arthrex received from surgeons on the handleability of Arthrex's FiberWire suture?
A. That it's easy to utilize.
Q. And what surgeons provided that feedback?
A. I have heard Dr. Burkhart say that.
Q. Anyone else?
A. Not directly to me, no.
Q. Have any doctors provided negative feedback to Arthrex on the handleability of Arthrex's FiberWire suture?
A. Yes.
Q. How many doctors have provided negative feedback

33

to Arthrex on the handleability of Arthrex's FiberWire suture?
A. I know of only one account.
Q. And who was that?
A. I believe, again, it might have been Dr. Burkhart.
Q. And what negative feedback did Dr. Burkhart provide to Arthrex on the handleability of Arthrex's FiberWire sutures?
A. That the nylon was too repetitious in the TigerWire.
Q. What does that mean?
A. It means there were too many wraps.
Q. And that affected the handleability of the suture?
A. That affected the feel.
Q. Is the feel like handleability, or is that another word for handleability -- feel?
A. Feel would fall under handleability; how does it feel in your hands.
Q. All right. So that's one criteria used for the handleability?
A. Right.
Q. As well as passing the suture through tissue or any other things you described?

BROOKSTEIN DECLARATION
EXHIBIT 18

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC.,
a Massachusetts corporation,

Plaintiff,

v. Case No: CA-0412457-PBS

ARTHREX, INC, a
Delaware corporation,

Defendant.
_______________________________/

VIDEOTAPE DEPOSITION OF ANN WATERHOUSE

TAKEN:	Pursuant to Notice by Counsel for the Plaintiff
PLACE:	Ritz Carlton Golf Resort 2600 Tiburon Drive Naples, FL 34109
DATE:	Wednesday, August 24, 2005
TIME:	Began: 8:55 a.m. Ended: 1:00 p.m.
BEFORE:	TRACIE L. MOUNTAIN-THOMPSON Court Reporter Notary Public State of Florida at Large

COPY

Q What does that mean?
A In the first paragraph, under suture weight, which is coating, it says, "Pearsalls makes the following statement about the NuSil coating applied to both our Arthrex FiberWIRE and other competitive product."
So they're demonstrating their processing of that coating by the statement that follows.
Q That statement is from NuSil, not from Arthrex?
A No. That's from Pearsalls.
Q All right. But just to be clear, the coating on the FiberWIRE product is MED-2174, right?
A Correct.
Q Okay. And in that last paragraph on page 2104, the second sentence says, "As noted (above) we cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures, and other parameters for the coating process. For each coating batch all these details are recorded in the batch documentation available to you and other customers."
Do you see that?
A Yes.
Q What does that mean?

A That means that that's the processing that they -- they put onto our product and it's describing that they do it to a certain viscosity. They do it at a certain speed and temperature. And they have other parameters for the coating process. So that coating process is an agreed upon process by their buyers, basically, so that's what it is. That's how it's actually done.
Q Does Arthrex and Pearsalls have an agreed -- an agreed detailed coating process?
A Not that I know of.
Q So how does Arthrex know how the FiberWIRE coating is applied to its FiberWIRE product?
A Specifically, they could ask for that batch record for each lot that is produced, but in general, they know the coating process because of the temperature and speed, and the parameters that Pearsalls uses coats that in an even manner, so it's an assumption.
Q Is it true that Pearsalls cannot measure the amount of coating on the FiberWIRE product?
MR. SABER: Objection. Inconsistent with the testimony.
BY MR. FALKE:
Q I'm just looking. It says -- on page 2104 it says, "We," and I assume that's Pearsalls; is that right?

A Correct.
Q "We," Pearsalls, "cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures and other parameters for the coating process."
A Correct.
Q So does Arthrex accept batches of FiberWIRE based on the coating?
MR. SABER: Objection. Vague. Confusing question.
BY MR. FALKE:
Q All right. Was Pearsalls representing to Arthrex that it cannot measure the amount of coating on the FiberWIRE product when Arthrex submitted this statement to the FDA in Exhibit 81?
A Can you repeat the question.
Q Sure.
Was Pearsalls representing to Arthrex that Pearsalls cannot measure the amount of coating on the FiberWIRE product when Arthrex submitted Exhibit 81 to the FDA?
A Yes, as a percentage.
Q As a percentage of what?

A The total weight of the suture.
Q Has Arthrex submitted any document to the FDA in any submission which details the coating process Pearsalls uses to coat any FiberWIRE suture?
A No.
Q Why not?
A Because we used the statement as a reference point so that we didn't have to submit anything about the coating process. We described it instead.
Q You say "the statement," which statement is that?
A On 2104, the statement that Pearsalls makes.
Q Okay. And then it says, in the last sentence on page 2104, "For each coating batch all these details are recorded in the batch documentation available to you and other customers."
Do you see that?
A Yes.
Q Is the reference to "you" in that sentence, does that refer to Arthrex?
A Correct.
Q Does Arthrex have any documents which reflect the details of the coating process for the batches of FiberWIRE it receives?
A Not that I know of.

Q Does Arthrex have the ability to obtain those documents?
A Yes.
Q So Pearsalls can determine the percentage -- cannot determine the percentage of coating to the total weight of the suture; is that right?
A Correct.
MR. SABER: Objection. Vague.
BY MR. FALKE:
Q I'm sorry, what was your answer?
A Correct.
Q And the reason they can't do that is because they can't measure the amount of coating on it; therefore, they can't measure the percentage of the amount of coating to the total weight, right?
A Correct.
Q I'm going to reask that question because the record is slightly unclear. So Pearsalls cannot determine the percentage of coating to the total weight of the suture; is that right?
MR. SABER: Could you read that question back, please.
(The court reporter read back the requested portion of testimony.)
MR. SABER: Objection. Vague. Asked and

answered.
BY MR. FALKE:
Q You can answer.
A Correct.
Q Okay. If you could turn to page 2130, please, in Exhibit 81.
I'm sorry, are you there?
A Uh-huh.
Q If you look at the last paragraph on that page, 2130, and in particular, the last sentence, it says -- excuse me, let me step back. The second to the last paragraph on page 2130, it says, in the last sentence of that paragraph, "The dyed polyester suture (D & C Blue No. 6) and di-peroxide silicone oil (coating) are pharmacologically inactive."
Do you see that?
A Yes, I do.
Q Does the di-peroxide silicone oil (coating) refer to the MED-2174 that's applied to the FiberWIRE product?
A Yes, it does.
Q And what does that mean "pharmacologically inactive"?
A Pharmacologically inactive means that it does not cause any reaction when tested.

Q What do you mean by "when tested"?
A We test according to 10993, which is cited in that paragraph.
Q Uh-huh.
A There are certain tests that you have to perform according to that based on the use of your product. When they test that, as an example -- and you've got both of the tests -- they test whether there is a reaction or -- a negative reaction or an adverse reaction as opposed to nothing happening.
Q Right.
A If it -- if there is nothing happening, they consider that pharmacologically inactive.
Q Has Arthrex made any representation to the FDA in any submission as to whether MED-2174 is absorbable in the body?
A No.
Q Do you know if MED-2174 is absorbable in the body?
A No.
Q No, you don't know?
A I don't know.
Q I think I asked this but I'm going to ask it again. And Exhibit 81 was submitted to the FDA by Arthrex, right?

A Yes, it was.
(Exhibit 82 was marked for identification.)
BY MR. FALKE:
Q Let me hand you Exhibit 82, which is a document with Bates numbers ARM001882 through 1884. Have you seen this document before?
A Yes, I have.
Q And what is Exhibit 82?
A This is the substantial equivalence letter for K010673.
Q And that reference, that K number, 010673, reverts to Exhibit 78, right?
A Correct.
Q And what is the purpose of this substantial equivalence letter, Exhibit 82?
A It's the FDA's way of granting you permission for sale of a product.
Q Okay. So through Exhibit 82 the FDA was granting Arthrex the permission to sell Arthrex FiberWIRE; is that right?
A Correct.
Q And Exhibit 82 is dated May 14th, 2001; is that right?
A Correct.
Q Did Arthrex sell FiberWIRE prior to May 14th,

BROOKSTEIN DECLARATION
EXHIBIT 19

Arthrex

April 26, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Mr. David Krause
Department of Health and Human Services, Public Health Service
Division of General & Restorative Devices
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Amendment to Original Pre-Market Submission 510(k) #K010673, Arthrex FiberWIRE™

On February 28, 2001 the Arthrex FiberWIRE™ was submitted to the FDA. Per a conversation between Ann Waterhouse (Arthrex) and David Krause (FDA) on April 16, 2001, the following is being sent as amendment information. Specifically included are percentages for content, labeling amendments, and research data for accessory equipment.

Arthrex has submitted in duplicate the requested information and respectfully asks that these be accorded the same confidentiality as the original submission, K010673. We request that the Food and Drug Administration keep confidential all information outside of the 510(k) summary and indications for use.

Should the following information be in any way deficient, please let us know. We will be happy to provide you with any missing details or information. Should you have further questions concerning the amendment we have submitted, please contact either Vernon Brown or Ann Waterhouse at (941) 643-5553. Thank you.

Sincerely,

Ann Waterhouse

Ann Waterhouse
Regulatory Affairs Specialist

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

ARM 002103

1. In many places in the document the suture is described as being composed of polyester and ultrahigh molecular weight polyethylene (UHMWPE). Please describe the polyester and indicate what percentage of the suture weight is UHMWPE. Also, what percentage of the weight of the suture is the dye and what percentage of the weight of the suture is the coating?

Description of the polyester:
The Polyester used by Pearsalls to produce Arthrex FiberWIRE™ is created from high tenacity filaments of Polyethylene Terephthalate. Specifically, this is type 712 polyester that is manufactured by KoSa GmbH & Co KG.

% of the suture weight which is Ultra high molecular weight polyethylene:
Broken into percentage, the Polyester is 38.09% of the suture input and the Polyethylene (UHMW) is 61.91%.

Suture weight which is dye:
In using an accepted dye, D&C Blue No. 6, neither Pearsalls nor Arthrex measured the percentage of weight which the suture gained by the dye process. Pearsalls certifies that the process with which they dye the polyester conforms with the 2.0 Cupric Sulfate listed in the USP Matching Solutions table on page 1585 of USP 24. Also, Pearsalls certifies to all of it's customers that the D&C Blue No. 6 is a FDA approved dye.

Suture weight which is coating:

Pearsalls makes the following statement about the NuSil coating applied to both our Arthrex FiberWIRE™ and other competitor product:

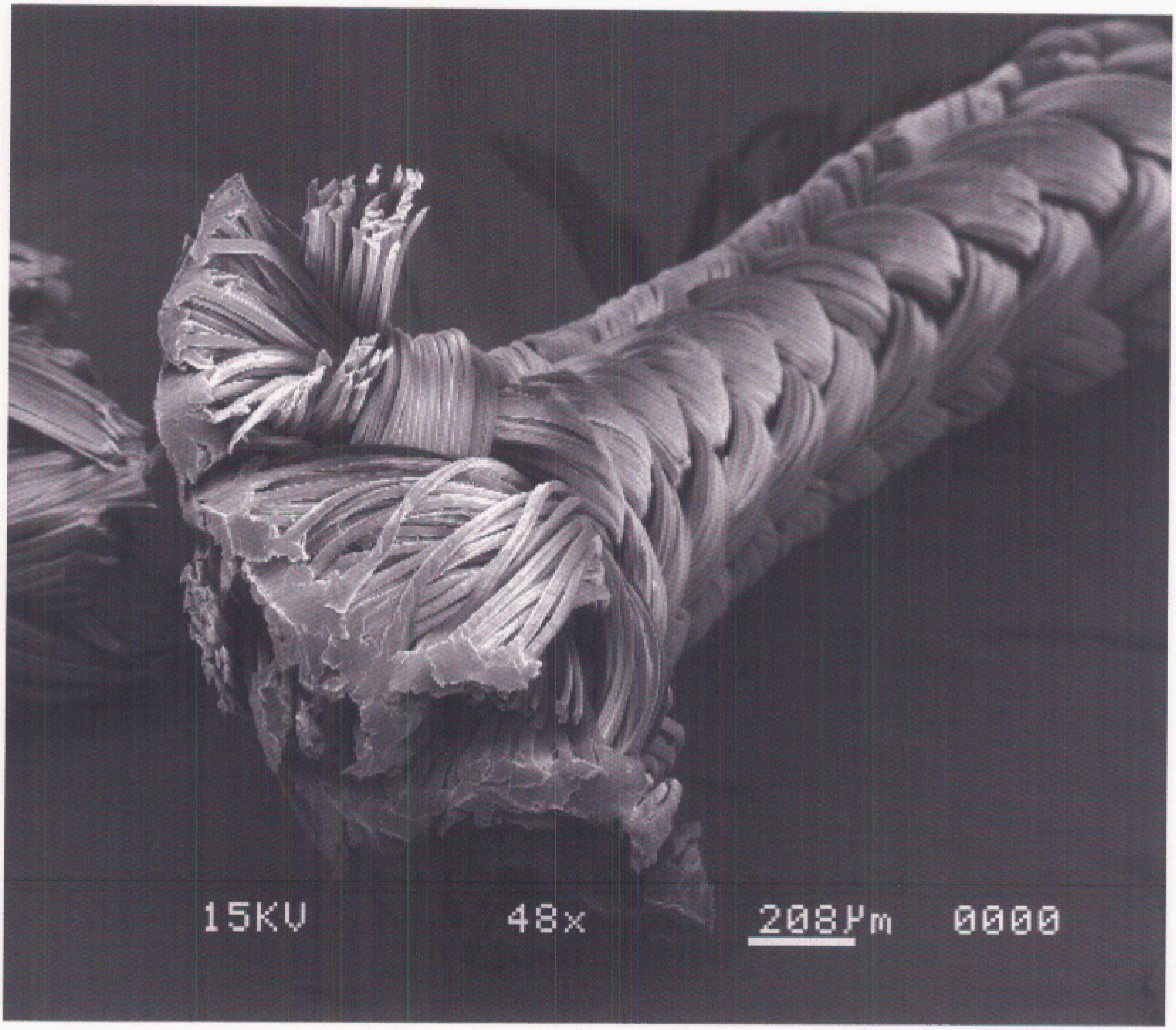
"The coating is a silicone rubber known as NuSil 2045. It is identical to the coating we apply for Davis & Geck silk suture, and is also used to coat "Ticron" polyester suture. As noted (above) we cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures, and other parameters for the coating process. For each coating batch all these details are recorded in the batch documentation available to you and other customers."

2. **You describe your suture as having a silicone elastomer coating. Please identify a legally marketed suture predicate that is coated with silicone.**

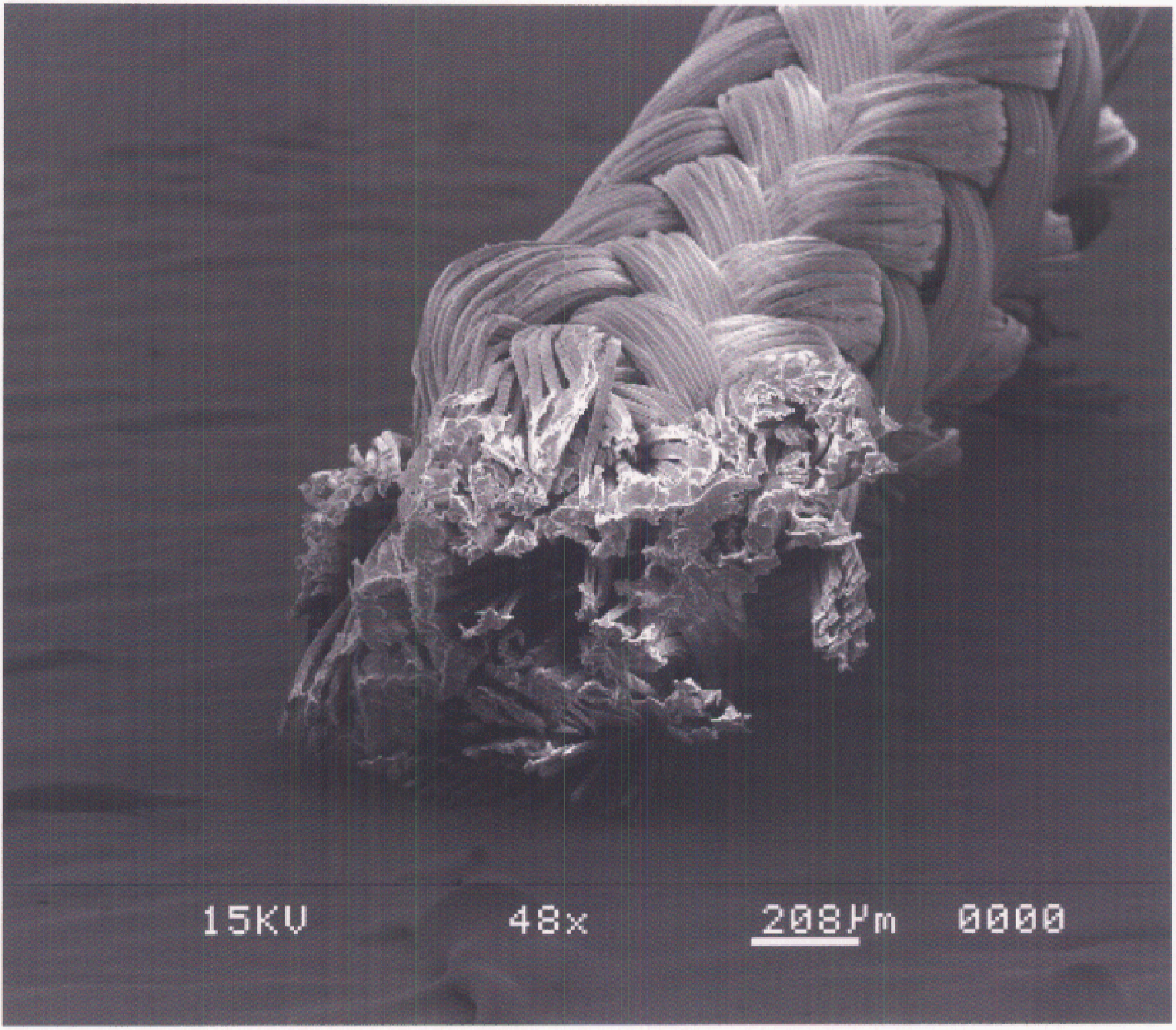
The predicate devices with Nu-Sil silicone derivative or equivalent, used to coat silk and polyester suture are listed below. The 510 (k) summaries or statements for these predicate products are contained in the following pages:

K930586	Dermalon, Surgilon, Ophthalon, & Ophthalmic Suture
K930590	Silk Sutures
K961925	Polyester Non-Absorbable Surgical Suture
K990088	Synthofil Non-Absorbable PET Surgical Suture
K001172	Polyester Non-Absorbable Surgical Suture
K003590	Grams Polyester Non-Absorbable Suture

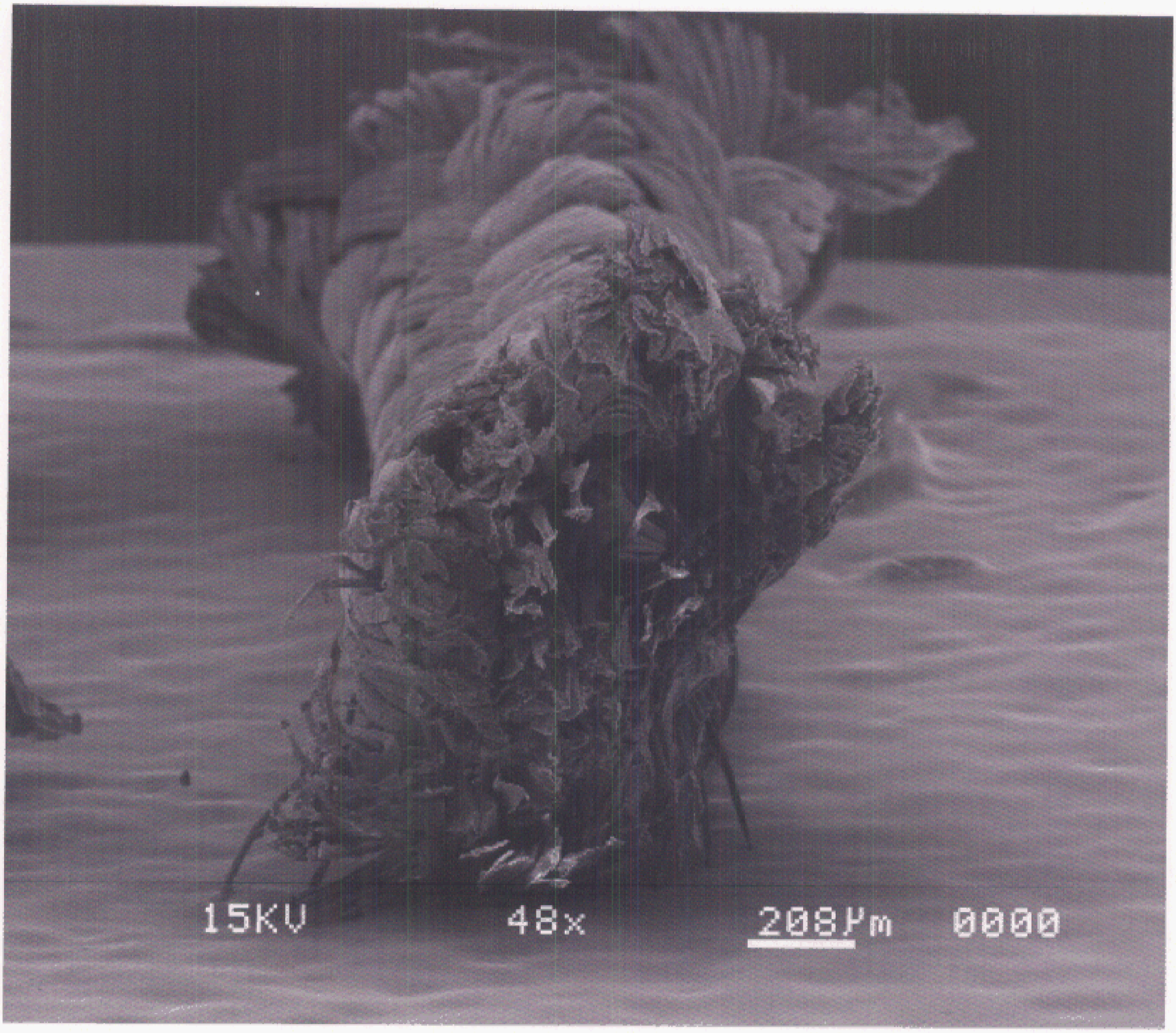
BROOKSTEIN DECLARATION
EXHIBIT 20


15KV
48x
208µm
0000

BROOKSTEIN DECLARATION
EXHIBIT 21


15KV
48x
208µm
0000

BROOKSTEIN DECLARATION
EXHIBIT 22


15KV
48x
208µm
0000

BROOKSTEIN DECLARATION
EXHIBIT 23

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-o-

DEPUY MITEK, INC., a Massachusetts Corporation,	:	Civil Action No. 04-12457 PBS
Plaintiff,	:	
-vs-	:	
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LTD., a Private Limited Company of the United Kingdom,	:	EXPERT DEPOSITION OF:
	:	ROBERT T. BURKS, M.D.
Defendants.	:	

-o-

Location: Mariott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

-o-

APPEARANCES

For the Plaintiff:

ERICH M. FALKE and
MICHAEL J. BONELLA
WOODCOCK WASHBURN, LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215)564-8987
(215)568-3439 (fax)
Efalke@woodcock.com

For the Defendant:

SALVATORE P. TAMBURO
DICKSTEIN SHAPIRO MORIN OSHINSKY
2101 L Street NW
Washington, DC 20037-1526
(202)822-5164
(202)887-0689 (fax)
TamburoS@dsmo.com

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INDEX

Witness	Page
ROBERT T. BURKS, M.D.	
Examination by Mr. Falke	4
Examination by Mr. Tamburo	99

-O-

EXHIBITS

(All Exhibits premarked by Mr. Falke)

Number	Description
231	Subpoena in a Civil Case
232	Expert Report of Robert Burks, M.D.
233	Curriculum Vitae
234	Chart of sutures
235	Sutures retained by Mr. Falke
236	Sutures retained by Mr. Falke
237	Sutures retained by Mr. Falke

-O-

June 7, 2006 3:05 p.m.

PROCEEDINGS

(Discussion off the record.)

THE VIDEOGRAPHER: We are on record at 3:05. This is the videotape deposition of Dr. Robert T. Burks taken on June 7, 2006 in the matter of DePuy Mitek, Incorporated, a Massachusetts corporation, versus Arthrex, Incorporated, a Delaware corporation.

The case number is 04-12457 PBS in the United States District Court for the District of Massachusetts.

My name is Donna Polton. I'm a licensed videographer. The court reporter is Denise Kirk. We represent the firm of Veritext Corporate Services.

Counsel will now state their appearances for the record and the witness will be sworn in.

MR. FALKE: Erich Falke and Michael Bonella from Woodcock Washburn representing plaintiff DePuy Mitek.

MR. TAMBURO: Salvatore Tamburo representing Arthrex Inc.

ROBERT T. BURKS, M.D.
Called as a witness herein, being
First duly sworn was examined
And testified as follows:

EXAMINATION

BY MR. FALKE:

Q. Good afternoon, Dr. Burks. How are you?
A. Good.
Q. Have you ever been deposed before, Dr. Burks?
A. Yes.
Q. On how many occasions have you been deposed?
A. Several. I don't know a number.
Q. More than five?
A. Yeah.
Q. Less than ten?
A. Reasonable.
Q. I'm just going to go over a few of the ground rules to make sure we're on the same page. Periodically we'll be taking breaks, roughly once an hour. But if there's any time you feel you need to take a break, let us know and we'll accommodate you as soon as we can.
Do you understand you've taken an oath to tell the truth today?
A. Yes.
Q. And that leads me to the next one. All answers, could you please make them verbal so that the

court reporter can transcribe them as opposed to shaking your head or nodding your head; do you understand that?
A. Yes.
Q. Also, if you'll allow me to finish the question before you answer, it will make for a better transcript. Even though you may even be able to anticipate the end of my question by what I say in the beginning, if you'd allow me to finish and then answer it will allow the reporter to make a clear transcript; do you understand that?
A. I do.
Q. Also, if I ask you a question and you don't understand, I'll ask that you tell me you don't understand the question. Otherwise, I'll assume that you did understand the question; is that fair?
A. Fair.
Q. Are you being represented today by counsel?
A. Yes.
Q. Who is your counsel?
A. Sal Tamburo.
Q. Do you know when Sal or the law firm Dickstein Shapiro Morin & Oshinsky began representing you for purposes of this case?

A. In February.
Q. Is that when Arthrex or Dickstein contacted you with respect to your role in this case?
A. Yes.
Q. Are you being compensated for the time you spend on this lawsuit?
A. Yes.
Q. How are you being compensated?
A. How much?
Q. Yes.
A. $400 an hour.
Q. Was that a negotiated fee or was that your standard fee for doing expert consulting?
A. I don't really have a standard fee, so I guess you could call it negotiated.
Q. Other than money, is there any other compensation you are receiving for work on this case?
A. No.
Q. Were you given any dollar amount that you should not exceed in performing work for Arthrex in this case?
A. No.
Q. I'm going to hand you DePuy Mitek Exhibit 231 and ask you if you recognize this document, Exhibit 231?

A. Yes.
Q. What is Exhibit Number 231?
A. A subpoena for me.
Q. Did you understand that be Exhibit 231 was a subpoena on you for certain documents and things listed in schedule A of Exhibit 231?
A. Yes.
Q. Today are you producing any documents or things in response to the subpoena, Exhibit 231?
A. No.
Q. If you could turn to page two of Exhibit Number 231, please. Do you see request number one for documents there, being all communications between any of Arthrex, you, Dr. Mukherjee and Dickstein Shapiro Morin & Oshinsky concerning the lawsuit commenced by the plaintiff attached as Exhibit 1?
A. Yes.
Q. Did you perform any search that might be responsive to request number one in Exhibit Number 231?
A. Yes.
Q. Did you find any?
A. No.
Q. Request number two in Exhibit 231 is all documents concerning this lawsuit, including, but not

limited -- well, hold on. Strike that.
Did you perform a reasonable search for documents in response to request number two in Schedule A of Exhibit 231?
A. I guess I don't see the difference. There aren't any documents that I'm aware of in the lawsuit.
Q. Under things to be produced on page two of Exhibit Number 231, request number one is all tested and untested samples referred to in Expert Report of Robert T. Burks, MD dated March 24, 2006, including, but not limited to suture A and suture B. Do you see that?
A. I do.
Q. Did you perform a search for things responsive to request number one?
A. No.
Q. You did not?
A. I knew it didn't exist.
Q. You knew what didn't exist?
A. The suture.
Q. You mean the tested and untested samples?
A. The pieces that I had I had disposed of when I was done. I knew there wasn't anything to look for.
Q. Under request number two on things to be

produced on page two of Exhibit 231 is all equipment used to test the samples as described in paragraphs nine through 13 of Expert Report of Robert T. Burks, MD dated March 24, 2006, including, but not limited to the equipment that was used to cut and wet the samples and to conduct the tactile feel analysis and knot tie-down analysis; do you see that?
A. I do.
Q. Did you perform a search for the materials requested in request number 2?
A. No.
Q. Why not?
A. The equipment that was used was a pair of scissors just to cut it, something from home, I felt like it didn't have relevance.
Q. What about the solution that was used to wet these tested samples?
A. I used tap water.
Q. Did you use anything else in performing the tests described in paragraphs nine through 13 of your expert report other than tap water and scissors and the sutures?
MR. TAMBURO: It might help if the witness had his report in front of him to refer to.
A. The things used, like a pair of gloves,

are disposed of after and they're just a generic set. There wasn't anything used that would be unique that I felt would be worthwhile to produce.
Q. So you used gloves when you performed the tactile feel analysis and knot tie-down analysis?
A. I did both. I used and didn't use gloves.
Q. Is there any reason why you decided not to bring gloves today?
A. No.
Q. Did your counsel advise you to bring gloves?
A. No.
Q. Did you go over -- did you have a chance to go over Exhibit 231 with your counsel before coming to today's deposition?
A. Yes, we looked at it.
Q. Dr. Burks, could you please describe your formal education post-high school for me, please.
A. I did medical school at St. Louis university. I guess after high school I did college at Southern Methodist University, medical school at St. Louis university, orthopedic training at University of California San Diego.
Q. When did you graduate from undergrad?
A. Undergrad college was '74.

Q. What about medical school?
A. '78.
Q. Then, after medical school, where did you go?
A. To residency training.
Q. When did you finish your residency training?
A. '83.
Q. Where was your residency training?
A. University of California San Diego.
Q. Did you have a specialty there?
A. Yes. Well, there's no specialty in training per se, but I did do a fellowship during that time with Dale Daniel at Kaiser Permanente.
Q. What was that fellowship in?
A. Knee and sports medicine.
Q. When did you finish your fellowship in knee and sports medicine?
A. '83.
Q. Other than those programs or degrees you mentioned, are there any other -- is there any other formal education that you've gone through?
A. No.
Q. Once you completed your fellowship in knee and sports medicine in 1983, what did you do?

A. I went into private practice in St. Louis, Missouri.
Q. What was the focus of your private practice in St. Louis?
A. Sports medicine, general orthopedics.
Q. Did you focus on any particular parts of the body within sports medicine and general orthopedics?
A. Knee and shoulder were the big focus.
Q. And when did you leave private practice in St. Louis?
A. I was there three years; I believe it was '86.
Q. Then what did you do in 1986?
A. I went to Wayne State University in Detroit.
Q. What did you do at Wayne State?
A. I was on the academic staff there and was the head of sports medicine.
Q. Your time spent at Wayne State, was that strictly in an academic environment or did that also include a clinical practice?
A. Yes. I mean, it was a clinical practice, but it was as a full-time faculty member.
Q. Can you explain how that works, your role

14

at Wayne State, how it was spent between full-time faculty member and participating in a clinical practice?
A. Well, there's really no distinction. I mean, my job was to take care of patients and people. And so the education was for residents and that's what they were training to do was take care of people.
So there really wasn't a distinction between a clinical practice and what you are doing academically as far as your work goes.
Q. So did you teach in a classroom setting?
A. No.
Q. So I think I understand. What type of medicine did you practice at Wayne State as a full-time faculty member and in a clinical practice?
A. It was orthopedic surgery with an emphasis in sports medicine.
Q. Again, did you focus on the knee and shoulder areas?
A. Yes.
Q. When you were at Wayne State what were the -- generally what were the procedures that you would perform for shoulder surgeries?
A. Perform shoulder instability operations, rotator cuff operations, things that we do for what we

15

call impingement, shoulder pain procedures, procedures that revolve around the clavicle.
Q. Anything else you can think of?
A. I mean, it's a pretty wide area, but those are the main things.
Q. What about when you were at Wayne State, what were the procedures that you would perform for knee surgeries?
A. Ligament reconstructions, operations for instability of the knee cap, cartilage procedures, meniscus procedures.
Q. When you were at Wayne State, did you perform any ankle surgeries?
A. Sure.
Q. What ankle surgeries? What procedures would you perform doing ankle surgeries?
A. The main procedures revolved around arthroscopy, and then I would do some procedures that revolved around loose ankle joints where people have chronic ankle sprains and tightening those up.
Q. Then, I take it, at some point you left Wayne State?
A. Correct.
Q. What year was that?
A. '88.

16

Q. In 1988 after leaving Wayne State, what did you do?
A. I came here to the University of Utah.
Q. What position did you enter the University of Utah in 1988?
A. I was an assistant professor in orthopedic surgery. And we didn't really have a true division, but I was part of the sports medicine team.
Q. Can you generally describe your duties as an assistant professor in the orthopedic surgery department at the University of Utah?
A. Duties were to take care of standard patients that we would see, to instruct residents in clinical evaluation of patients and surgical treatment of patients, to be involved in some areas of research and produce academically, and were involved with taking care of the athletic teams.
Q. While at the University of Utah, I take it from 1988 to the present you've remained at the University of Utah?
A. Yes.
Q. From 1988 to the present, do you perform any classroom teaching?
A. Minimally. Occasionally it comes up, but not very much.

17

Q. What classes would you teach when it comes up?
A. It's usually just an isolated lecture, not like a class series. So it would be lectures to the residents or to medical students on a specific topic, sometimes to physical therapy students.
Q. Since 1988, how have your duties and responsibilities at the University of Utah changed?
A. I don't think they've changed much.
Q. Okay. At some point you did become head of the sports medicine division, though, right?
A. Correct.
Q. Do you know when that happened?
A. I'd be guessing a little. I'm not sure of the exact year.
Q. How about 1992, does that sound familiar?
A. That's probably close.
Q. Dr. Burks, I'm going to hand you Exhibit Number 233. This is a printout of a web page from the University of Utah. If you could just please look at that.
MR. TAMBURO: Do you have another copy?
Q. No. Just let me know if that's generally accurate.
A. Yes.

Q. Dr. Burks, can you describe for me your relationship with Arthrex, Inc.?
MR. TAMBURO: Objection, vague.
A. I am a consumer. Over the years I have been an advisor for different products. That's it.
Q. You say you are a consumer of Arthrex products. What Arthrex products do you use?
A. Well, we use things like drill guides, use suture anchors and sutures, drill bits. That's it.
Q. Do you use any Arthrex knee fixation devices?
A. I have used Arthrex knee fixation devices but don't currently use any.
Q. What did you use?
A. They have an interference screw that is metal and one that is absorbable that I used to use that I don't use now.
Q. Earlier you said things like we used things like drill guides, suture anchors, and sutures, drill bits. Who were you referring to when you said "we"?
A. I guess it was the generic "we" of the sports medicine service.
Q. Do you personally use those Arthrex products?

A. Oh, yes.
Q. Do you have any consulting agreements with Arthrex?
A. To be honest, I'm not sure of the direct answer to give you on that. I have a couple of pieces of equipment that I have worked with them on in developing, so that might be considered a consulting agreement.
I'm not a consultant, just a generic like on a board of advisors or something like that.
Q. I don't understand when you say "I have a couple of pieces I equipment I worked with them on in developing so that might be considered a consulting agreement", could you explain that?
A. Well, I went to them to develop a guide for a knee ligament reconstruction. They liked the idea. They made the guide. They have the guide as one of the products that they sell, and then I get some royalty from their sales.
Q. Okay. So other than services you performed for this case, have you received money from Arthrex for other services such as, for example, this work you did with the guide?
A. I think I just said I get royalties for that.

Q. Other than royalties and other than money for your work you've performed in this lawsuit, do you receive any other money from Arthrex?
A. No.
Q. How many different pieces of Arthrex equipment to you receive royalties on?
A. There is a knee ligament guide system that has a few different pieces in it. So I can't give an exact number. It's sort of a guide system with four or five different pieces, parts of it.
There is a screw that we use for augmenting ligament fixation that I get some royalties on along with those guides.
Q. Do you know what the trade name is for the knee ligament guides that you receive royalties from Arthrex on?
A. It's kind of silly that I wouldn't be able to give you that. It's for posterior cruciate ligament reconstruction.
Q. And do you know what the trade name is on the screw that you receive royalties from Arthrex on?
A. I don't.
Q. For what area of the body is this screw used on?
A. It could be used anywhere, but I think the

large majority would be at the knee.
Q. Are you the named inventor on any patents?
A. No.
Q. The screw that you developed with Arthrex, is that used for the ACL or PCL?
A. Can be either.
Q. Is that an interference screw?
A. No. It's a screw we typically refer to as a post. And what that means is that suture from a ligament or tendon gets tied around this to help hold it while it's healing in.
Q. You also said, in describing your relationship with Arthrex, you used the word "advisor". We've just been talking about you developing certain equipment. Is that what you meant by advisor?
A. Yes.
Q. Do you advise Arthrex in any other way other than what we've just talked about with respect to developing equipment?
A. No.
Q. Do you know Dr. Paul Fenton from Toledo, Ohio?
A. I don't.
Q. What about Dr. Marlow Goebel?

A. I do.
Q. How do you know Dr. Goebel?
A. Dr. Goebel practices in Logan, and is an adjunct faculty here at the University. So I've known him pretty much since I came here in '88.
Q. Does Dr. Goebel have a reputation in the field?
A. Sure.
Q. Do you know that reputation is?
A. Well, I know my perception of his reputation. I think he is a very inventive, unique-thinking orthopedic surgeon who has focused his career on knee surgery.
Q. What about Dr. Richard Greenwald, not a medical doctor, but I believe he's a PhD?
A. No.
Q. Generally speaking, how much in royalties have you received from Arthrex for your work in developing the equipment that we've just talked about?
A. I couldn't give you an exact number, but I would say the royalties in a given year probably fluctuate between seven and ten or $11,000.
Q. Have you ever been to Naples, Florida to visit Arthrex?
A. Yes.

Q. On how many occasions have you gone to Naples to visit Arthrex?
A. I believe twice.
Q. What did you do when you went to Arthrex?
A. One of the visits was a meeting which had orthopedic surgeons from the United States and Europe and some South America. And it was an academic meeting but, obviously, focused on Arthrex things.
One time was just as they had opened their new manufacturing plants and facilities and it was to tour and visit.
Q. When was the first time you were at Arthrex?
A. I'd be guessing. I'm going to say maybe six years ago.
Q. When was the second time you visited Arthrex?
A. About two or three years ago.
Q. How many years have you been receiving royalties from Arthrex on the knee ligament guide?
A. I don't know for sure. I'm going to say five.
Q. How many years have you been receiving royalties from Arthrex on the screw?
A. Probably similar, maybe a year longer.

Q. When you went to Arthrex, who paid for the visits?
A. The meeting that was held was paid for by Arthrex. The other visit, I don't honestly remember how I got down there.
Q. The first time you went to Arthrex, how many days did you stay down in Naples?
A. I'm going to say two.
Q. The second time?
A. Two to two and-a-half.
Q. Other than a consumer and advisor, how else would you describe your relationship with Arthrex?
A. I've known the president of the company since near the beginning of the development of the company. So I've had interactions suggesting things that might be beneficial to look at or might improve patient care in certain circumstances. I've had that kind of relationship, I think.
Q. Anything else?
A. No.
Q. How long have you been a consumer of Arthrex products?
A. Well, from pretty much when they got rolling, which I don't remember exactly, I'm going to say like 1990, but I don't know for sure.

Q. Would you say you use more Arthrex products now than you did ten years ago?
A. Certainly.
Q. Why is that?
A. They have more products now than they did ten years ago.
Q. Any other reason?
A. I like the products.
Q. Anything else?
A. No.
Q. Dr. Burks, I'm going to hand you DePuy Mitek Exhibit 232 . Could you identify Exhibit 232 for me please?
A. 232 is my report to Sal Tamburo and my CV.
Q. Did you write Exhibit Number 232?
A. Well, I certainly had a hand in writing the CV. The other part of the report was written after conversation with Sal, by Sal.
Q. So you talked to Sal and then Sal wrote the report and then did you sign it after it was written by Sal?
A. Sal and I talked about the report, he wrote it, I reviewed it, had to make some changes here and there on background and what not, and then

conversed with him about that and then signed the final.

Q. What changes did you make to the report after Sal initially drafted it?

A. I don't remember specifics, but I think some of the background of when I did this or where I was or something hadn't been finished, but I don't remember the other specific changes.

Q. Do you know if there are any drafts of Exhibit 232?

A. I don't have any.

Q. Do you know if any exist?

A. I don't know.

Q. How was the initial draft prepared by Sal sent to you?

A. E-mail.

Q. E-mail?

A. Yes.

Q. And then what did you do with the e-mail?

A. Made a few changes and -- to be perfectly honest, I can't remember if I made changes and sent them back or got on the phone and said, hey, here's where I would fill in this or change that. I don't remember.

Q. Do you remember physically or

electronically changing the word document and sending it back to Sal?

A. I don't remember doing that.

Q. Do you remember printing it out?

A. I don't.

Q. Do you remember if you read it on the screen or did you read it in hard copy form?

A. I certainly read it on the screen. I can't remember if I made changes based on what was on the screen or if I just got on the phone and the changes were made then.

Q. But you are pretty sure you didn't print it out and make handwritten comments on it?

A. Right, right. Yes.

Q. Let me ask you a better question: Did you print out the e-mail that Sal sent you of the initial draft of the report and then make handwritten comments on it?

A. No.

Q. Do you remember when you signed the report?

A. Without looking at any data on it, I don't have a specific.

Q. Feel free to look at the data.

A. Okay.

Q. Let me ask you the question again. Do you remember when you signed the report, Exhibit 232?

A. I will say March 24, 2006.

Q. Do you remember what time of day you signed Exhibit Number 232?

A. No.

Q. Do you remember where you were when you signed Exhibit 232?

A. I'm sure I was somewhere in my office.

Q. Once you signed Exhibit 232, did you fax it back to Sal?

A. I don't remember.

Q. Do you remember signing it in the morning?

A. I don't remember.

Q. Do you remember signing it in the afternoon?

A. No, I don't remember that.

Q. Do you remember signing it at night?

A. I don't. It wasn't a huge event in my life so I. . .

Q. So once it was signed, do you remember how it was communicated back to Sal? Was it faxed or was it overnighted?

A. To be honest, I don't remember.

Q. In the course of preparing the report, did

you review any documents concerning this case?

A. No.

Q. Other than Sal, did you speak with anybody else about the preparation of Exhibit 232?

A. No.

Q. Did you speak to Dr. Mukherjee with respect to preparing Exhibit Number 232?

A. No.

Q. Did you speak to any Arthrex employee in preparing Exhibit 232?

A. No.

Q. With respect to this present case, have you ever spoken to Dr. Mukherjee?

A. No.

Q. With respect to this present case, have you ever had any communications with Dr. Mukherjee?

A. No.

Q. No e-mails?

A. I don't know Dr. Mukherjee.

Q. How did you prepare for today's deposition, Dr. Burks?

A. I had a meeting with Sal Tamburo.

Q. Anything else?

A. No.

Q. When did you meet with Sal Tamburo for

30

preparation of today's deposition?
A. Last night.
Q. Where did you meet?
A. Here.
Q. At the hotel?
A. Yes.
Q. For about how long did you meet with Sal in preparation for today's deposition?
A. Two hours.
Q. Did you have a chance to speak with Mr. Tamburo today about preparing for today's deposition?
A. No.
Q. When you met with Mr. Tamburo last night for about two hours, what did you discuss?
A. We talked about the report, talked about basics on depositions, that it would be a video deposition, etc. I can't remember, really, any other specifics.
Q. What did you talk about when you talked about the report?
A. I think it was more just what probably would be the basis of questions, i.e., background, questions of, you know, how things were done, questions of relationships, things like that.
Q. When you say "how things were done", what

31

are you referring to?
A. Just methods of looking at the suture.
Q. And how you performed the tests?
A. Uh-huh.
Q. Dr. Burks, could you please turn to paragraph six in Exhibit 232. Are you there?
A. Yes.
Q. Can you please describe the characteristics of a surgical suture that are generally important to an orthopedic surgeon?
A. I think importance would be that it's compatible with the body so that there aren't significant reactions, strength.
Q. You mean biological reactions?
A. Yes. Strength of the suture is important, how a suture handles, passes through tissue and ties is important.
Q. Anything else?
A. Probably hundreds, but that will cover it.
Q. Other than compatible with the body, strength, handles well and passes through the tissue, sitting here right now can you tell me any other characteristics of a surgical suture that are generally important to an orthopedic surgeon?
A. Sure. There are certain circumstances

32

where it needs to be visible.
Q. Continue.
A. What else would be important to me? Size of the suture is important, obviously.
Q. I'm sorry, just so we're on the same page, my question was not directed to what's important to you but what's important to an orthopedic surgeon as written in paragraph six of your report, Exhibit 232.
A. Okay. I'm an orthopedic surgeon so I was thinking what would be important to me and what would be important to other orthopedic surgeons.
Q. Okay. So what you wrote in Exhibit 232, paragraph six, the first sentence, it says: "I may describe the characteristics of a surgical suture that are generally important to an orthopedic surgeon."
When you say "to an orthopedic surgeon" there, are you referring to a generic orthopedic surgeon or are you referring to yourself?
A. I would say my opinion of those characteristics for an orthopedic surgeon, of which I am one.
Q. So those characteristics are generally important to you or to another orthopedic surgeon?
A. I think both.
Q. Because there's some things that you might

33

consider important but another orthopedic surgeon might not consider important, is that right?
A. That would be true.
Q. So then in first sentence of paragraph six -- I'm still trying to understand -- you may describe characteristics of a surgical suture that are generally important to you or to another orthopedic surgeon?
A. I would describe what my experience would tell me that most orthopedic surgeons feel is important and what I also feel.
Q. Now, when you say "my experience would tell me that most orthopedic surgeons feel", what is that experience based on?
A. It's based on over 25 years of doing this.
Q. Okay. Is that experience based on any surveys you've read or conversations you've had with other orthopedic surgeons where they've told you that they think these particular characteristics of a surgical suture are important?
A. I don't know that I could specifically relate to surveys but, certainly, there are conversations and discussions about it.
Q. Have you read any surveys describing the characteristics of a surgical suture that are

generally important to an orthopedic surgeon?
A. Not that I remember.
Q. Have you conducted any surveys describing the characteristics of a surgical suture that are generally important to orthopedic surgeons?
A. No.
Q. Other than compatibility with the body, strength, handling, passing through tissue and size, are there any other characteristics of of a surgical suture that are generally important to an orthopedic surgeon?
A. I also mentioned knot tying.
Q. Is knot security an important characteristic of a surgical suture?
A. Sure.
Q. Why is that?
A. Well, if you tie a knot you intend to have a suture have a certain amount of tension in it and if you don't have knot security, you probably won't have that tension.
Q. Anything else?
A. No.
Q. Is knot strength an important characteristic of a surgical suture?
A. Sure.

Q. Why?
A. Same.
Q. Same as what?
A. Same as what I just said.
Q. Do you know what the term "knot profile" means?
A. I think I do.
Q. What's your understanding of the term knot profile?
A. My understanding would be after a knot is tied, the suture frequently is wrapped around itself. And knot profile would be how large that knot generally appears after the knot has been tied and cut.
Q. Is knot profile and knot height considered the same thing, based on your experience?
A. I suppose they could be fairly close.
Q. Is knot height and knot profile an important characteristic of a surgical suture?
A. I think it would be fairly low on the grade if you were to mark it.
Q. Is it considered an important characteristic of a surgical suture? Is knot height and knot profile considered important characteristics of a surgical suture?

A. Sure.
MR. TAMBURO: Objection: considered by Dr. Burks or who?
Q. I think he can only testify for himself. So based on your opinion, the answer is the same?
A. Sure.
Q. All things being equal, a suture that has a lower knot profile would be considered advantageous over a suture that had a higher knot profile, is that generally correct?
A. If one were to say all other things are equal, then sure.
Q. Based on your experience in orthopedic surgery is it better to have fewer knots in a suture when performing surgery?
A. You might have to work on that one again. I was just going to get a clarification of the question.
Q. We'll come back to that one. You said strength is an important characteristic of a surgical suture; why is that?
A. If the suture breaks, it doesn't do you any good.
Q. Anything else?
A. No.

Q. You also said that handling is an important characteristic of a surgical suture?
A. Sure.
Q. Why is that?
A. If you imagine trying to sew a suture together with a lead wire, it would make it much more difficult. So having flexibility and maneuvering is important.
Q. As you use the term "handling", what are you referring to?
A. The ability to manipulate a suture, to place a suture where you would like it to be, to be able to pull it together to tie knots.
Q. Anything else?
A. No.
Q. You also said that passing through tissue is considered an important characteristic of a surgical suture. Why is that?
A. Some tissues are more delicate or maybe more damaged in a way that if a suture doesn't pass through well and it takes sawing back and forth or pulling, it might damage the tissue you are trying to repair.
Q. You also said visibility is an important characteristic of a surgical suture. Why is that?

A. If you are putting sutures into a structure to fix it and you tie one down and can't really see where it is, you may not know how to place your next suture relative to the first one.
Q. In your experience, what makes a surgical suture more visible than another?
A. Color.
Q. Anything else?
A. I think mostly color.
Q. Are you familiar with the suture knot configurations identified by number, like a two -- two equals two or three equals two equals one or four equals one equals one? Is that nomenclature -- do you understand that?
A. I'm not -- I would answer that by saying I'm not sure. I think I know what you are talking about.
Q. What do you think I'm talking about?
A. Well, sometimes when people tie knots and they talk about how many half hitches they may place in a knot they may say you put two one way, one another way and two another way and it may be sort of an two-one-two or something.
I'm not sure if that's how you are meaning it, but I've seen that before.

Q. In that situation would a knot with less half hitches be considered better than a knot that has more half hitches?
A. No.
Q. Why not?
A. Well, the first important thing we talked about is the security. So, for example, I could throw one half hitch which would be fewer half hitches but that knot won't hold. So fewer is not necessarily better.
Q. Assuming that two knots have the same knot security, would the knot with the fewer amount of throws be considered better?
A. I don't think I'd necessarily say that.
Q. Why not?
A. I think the main thing that's important is that the knot holds what it's supposed to hold. I think the extra throw or two is so minor that it's many times hard to know is three enough, is four enough, is five enough? We may say we don't want to take any chances and put one or two more in.
So I don't think it's too important whether you do that or not.
Q. You also said size was an important characteristic of a surgical suture. First, what do

you mean by size?
A. Diameter.
Q. Why is that important?
A. Well, if I was to take a shoe string and try to sew your eyelid, that would probably be a problem.
Q. Did does that mean the smaller the diameter the better?
A. No.
Q. Can you explain that then.
A. It means that diameter should be appropriate for the location that a suture is being used and the requirements that you are placing on it.
Q. For a given procedure, do you have a certain number of half hitches you use when tying a knot?
A. No.
Q. It varies?
A. Yes.
Q. It varies on what?
A. My per --
Q. Go ahead, I'm sorry.
A. My perception of how well I've tied the half hitches before, and so I may be doing something that I think I didn't reverse it right or didn't make

it as tight and I want or whatever so I might want to throw more half hitches on it.
Q. For a given procedure, what are the ranges of number of half hitches you throw in a knot -- is that right?
A. Sure. The number would vary very largely because when we tie arthroscopically we many times use a complex knot as the first knot so it's not just a half hitch. But sometimes you can't do that and so you do have to just use half hitches. So if you are only doing half hitches, obviously, you would throw several on.
If you are doing a complex knot, then you may not need as many half hitches to back it up.
Q. When you say "complex knot" is that a particular knot or are you just referring to --
A. Yes.
Q. That's a particular knot configuration?
A. Correct.
Q. And you've heard the term surgeon's knot?
A. Yes.
Q. What is a surgeon's knot?
A. Well, surgeon's is simply like a half hitch throw only you throw it twice so that you have more friction between the suture when you are trying

to apply tension.
Q. Is that different than a square knot?
A. Yes.
Q. What's a square knot?
A. Describe a square knot. It's an over-under-under-over half hitch throw. A surgeon's knot is not a knot from the standpoint of a final product.
So a square knot -- when you tie a square knot you could argue you have a final product. You are not as done. But with a surgeon's throw, all you are doing is making it tighter so that you can now throw another throw to help finish the knot and lock it in place.
Q. What is a throw?
A. Like a half hitch.
Q. What is a half hitch?
A. It's taking suture and looping it around the other limb of the suture.
Q. Is it similar to tying a shoe, the first part of tying a shoe? Do you understand what I'm saying?
A. Yes. Actually, if you are tying a shoe, for the first throw if you did it twice and pulled it, that's a surgeon's. And so that's what that means.

So the single throw can be a half hitch but, obviously, when you tie your shoe, you lay it down a little flatter than what we do when we operate.
Q. For a given knot, what is the range of number of half hitches you throw?
MR. TAMBURO: Objection, vague.
A. If I throw a complex knot, then I usually put two to four half hitches behind it. If I can't throw a complex knot and I'm just throwing half hitches, then I probably would be in the six to seven range.
Q. The purposes of the two to four half hitches behind the complex knot, is that to hold the complex knot?
A. Correct.
Q. And then when you just do six to seven half hitches that's just -- that's its own that holds itself?
A. Correct.
Q. Why not do more than six to seven half hitches or more than two to four half hitches behind a complex knot?
A. There have been studies done on multiple different types of knots and backing it up. And I think that that is a reasonable number to be safe that

you have knot security without taking the extra time to throw extra half hitches that maybe are not helping you.
Q. So the goal is to secure the knot, correct?
A. Correct.
Q. What's the disadvantage of throwing ten half hitches versus only throwing five half hitches?
A. My time.
Q. Anything else?
A. Patient's time.
Q. Anything else?
A. All our time.
Q. Anything else? Is there a medical reason why you wouldn't use ten half hitches or five half hitches?
A. No.
Q. Does it affect the patient? Does it take up real estate in the body?
A. Well, clearly, if you were talking about the entire human body there are places where, clearly, taking up real estate could be a problem.
Q. I'm talking about shoulders.
A. Right. I don't think there's much that I do that that's a big concern. But I think you are

asking why not do ten or 12 and, clearly, you could get to the ridiculous and have a rope braided and there's no point in that.
MR. TAMBURO: When you get to a convenient point.
Q. (By Mr. Falke) Does having too many half hitches in the body or too many throws in the body delay healing of the tissue?
A. No.
MR. FALKE: Let's take a break.
THE VIDEOGRAPHER: Off record, 4:08.
(Brief recess.)
THE VIDEOGRAPHER: On the record, 4:21.
Q. Dr. Burks, in Exhibit 232, paragraph six, you state: "I may also describe the specific features of FiberWire that I find beneficial in my practice"; do you see that?
A. Yes.
Q. Would you describe the specific features of FiberWire that you find important?
A. I think the most important feature is its strength, so that it's difficult to break.
Q. Other than strength, what are the specific features of FiberWire that you find beneficial?
A. Well, I think it provides many of the

other features that we talked about that you'd like to see in a suture but it does it in a way that it is a very strong suture which makes it much easier to work with.

Q. What other features that we talked about apply to FiberWire that you find beneficial?

A. I guess what I'm meaning is that the features we talked about such a handleability, passing through tissue. knot tying. etc.. I find those features to be good, but what distinguishes it for me primarily is its strength.

Q. I'm just trying to be specific here. You said handleability, passing through tissue. knot tying, etc. When you say "etc.", what other features that we talked about apply to FiberWire?

A. I would say all the features that we talked about that you got done writing down. If FiberWire didn't meet those, then its strength might not be important; but since it does meet those and it is stronger than other sutures, then it becomes a preference.

Q. What suture did you use before FiberWire came onto the market?

A. For permanent suture we primarily used EthiBond.

Q. Let me rephrase the question. What suture did FiberWire wire replace in your practice?

A. It replaced EthiBond.

Q. Anything else?

A. Well, there are other companies that make sutures that are like EthiBond. EthiBond is almost like Kleenex where you say EthiBond and you actually might be using a suture from another company but we call it EthiBond. But that's primarily what it replaced.

Q. Is EthiBond manufactured by Ethicon?

A. Yes, but due to suture costs and bidding wars, there are other companies that make similar to EthiBond-type suture and we may have used those as well in the past.

Q. Is FiberWire stronger than Herculine?

A. I don't know the answer to that.

Q. Is FiberWire stronger than MaxBraid?

A. I don't know.

Q. Is FiberWire stronger than OrthoCord?

A. I don't know.

Q. Have you ever used Herculine?

A. I have.

Q. Have you ever used MaxBraid?

A. No.

Q. Have you ever used OrthoCord?

A. Yes.

Q. When have you used Herculine?

A. Herculine is a Linvitek product and so if I use a Linvitek anchor the Herculine comes with it and so that would usually be the time I'd use it.

Q. When do you use OrthoCord?

A. Same thing. OrthoCord is a Mitek product so if I use that I usually get the OrthoCord with it. I sometimes use three strands of OrthoCord when I don't need an anchor and I'm just sewing two tissues together.

Q. Do you like OrthoCord?

A. Yes.

Q. Why do you like OrthoCord?

A. I think for the same reason I like FiberWire. It's a very strong, hard-to-break suture.

Q. Does OrthoCord also have the characteristics of good handleability?

A. Yes.

Q. Does OrthoCord also have the characteristics of passing through suture well?

A. Yes.

Q. Does OrthoCord tie knots well?

A. Yes.

Q. Does it have good knot security?

A. Yes.

Q. Does it have good knot strength?

A. Yes.

Q. If we could turn to paragraph seven, please, in Exhibit 232. Are you there?

A. I am.

Q. You state: "I've been using FiberWire suture in my surgical procedures since 2001." What surgical procedures do you use FiberWire in?

A. I use FiberWire in most of the surgical procedures I do.

Q. Which ones are they?

A. I use it with shoulder replacement. I use it with rotator cuff repair. I use it with shoulder instability, knee ligament surgery.

Q. What knee ligament surgery do you use FiberWire in?

A. We use FiberWire whenever we want to repair torn ligaments back down to bone.

Q. You also say in exhibit seven of 232: "Most of my subjective use of FiberWire occurs during surgery and in the surgical environment. FiberWire is generally wet."

What do you mean by "subjective use"?

50

A. Poor wording. I guess it was to say that my sense of how FiberWire works and handles, that subjective feel of that is in that environment.
Q. So you don't use FiberWire in any non-surgical environment, do you?
A. Well, I've used FiberWire in laboratory studies when we do cadaveric studies or other things. But I don't use it for non-medically related things.
Q. When you say "most of my subjective use of FiberWire occurs during surgery", were you referring to the surgical environment versus non-surgical environment like you just described?
A. Right.
Q. Then you say "FiberWire is generally wet in the surgical environment", what does that mean?
A. Well, in the environment where I work arthroscopically we work with fluids, so it's hard for a suture not to be wet.
Obviously, there are times where we work in a dry air environment and the suture may get wet passing through tissue, but it's not necessarily intentionally wetted like it is with arthroscopy.
Q. During surgery, do you wet FiberWire before is it's introduced into the body?
A. Not deliberately, no.

51

Q. Earlier you said the suture may get wet passing through tissue, but it's not necessarily intentionally like it is with arthroscopy. I don't know what that means.
A. In an arthroscopic environment we have a microscope in a joint and we distend the joint so we can see with fluid.
So any time we introduce suture into that environment it's under water, if you will. So no matter what we do with it, by the time we start to use it, it's wet.
Q. When using FiberWire in a surgical environment, do you always wear gloves?
A. Yes.
Q. What about in the -- let me rephrase the question. In a nonsurgical environment, do you always wear gloves when using FiberWire?
A. No.
Q. What determines whether you wear gloves?
A. Either sterility for a patient or protection for myself.
Q. If it's a nonsurgical environment, how does sterility of the patient matter?
A. It doesn't.
Q. In a nonsurgical environment, what

52

determines whether you wear gloves?
A. In a nonsurgical environment it would be protection for me.
Q. Okay. Protection from what?
A. Well, if we do cadaveric surgery some cadavers have diseases so we may want to have gloves on when we work with them.
Q. What about in the laboratory environment, when you are using FiberWire, do you wear gloves?
A. I guess it depends on what you mean by the laboratory environment.
Q. By laboratory environment, I mean anything other than a surgical or nonsurgical environment like we've been talking about.
A. Well, we do, for example, cadaveric surgery in the laboratory, so we would consider that a laboratory environment, and I would use gloves for self-protection in that setting.
Q. Let me ask you a better question. Outside of a surgical environment or nonsurgical environment, do you wear gloves when using FiberWire?
A. I guess I would say no.
Q. Dr. Burks, if you could turn in Exhibit 232 to paragraph eight, you state: "Sometime in February 2006 I was contacted by attorneys for

53

Arthrex, Inc., and asked to conduct a tactile feel analysis as well as a knot tie-down analysis of coated and uncoated FiberWire suture. I agreed to conduct the analysis." Do you see that?
A. I do.
Q. Who contacted you in February of 2006?
A. Sal Tamburo.
Q. Anyone else?
A. No.
Q. Do you remember the substance of the conversation you had with Sal in February of 2006?
A. Yes.
Q. What was that substance?
A. He said that Arthrex and more, in particular, FiberWire was involved in a patent infringement lawsuit and he was wondering, since I've had experience of using FiberWire, if I would be willing to talk about FiberWire and how its used, etc., and if I'd be willing to look at FiberWire in a couple of different states and give him feedback on what I thought about that.
Q. What were those couple different states?
A. My understanding was that it was a coated suture and a not-coated suture.
Q. Anything else?

54

A. No.
Q. Do you know why Sal contacted you as opposed to another orthopedic surgeon?
A. No.
Q. During the conversation you had with Sal in February of 2006, did he suggest that you conduct a tactile feel analysis and a knot tie-down analysis?
A. Yes.
Q. Did he suggest any other tests to do on coated and uncoated FiberWire suture?
A. No.
Q. Did you suggest any other test to perform at that time, in February of 2006?
A. No.
Q. At any time did you suggest doing a test other than a knot tie-down or tactile feel analysis for purposes of this litigation?
A. No.
Q. At any time did anyone suggest to you to do a test other than a knot tie-down or tactile feel analysis for purposes of this litigation?
A. No.
Q. Do you know why they suggested that you perform a tactile feel analysis and knot tie-down analysis?

55

A. Not specifically.
Q. Generally do you know?
A. Generally. My general perception is they were wanting to determine if the suture seemed different with one treatment versus another.
Q. What do you mean by "seemed different"?
A. Well, it was a subjective assessment on my part if it seemed like the sutures handled differently or tied differently.
Q. Anything else?
A. No.
Q. Do you remember anything else from the conversation you had with Sal in February of 2006 when he called you and asked you to perform these tests?
A. No.
Q. So after that conversation, what was the scope of your assignment?
A. I actually told Sal that it would be my preference that he send me these two sutures that, you know, without specific labeling and that I would then work with those two different specimens and call him back and say this is what my feelings are.
Q. Uh-huh. Other than the tactile feel analysis and the knot tie-down analysis reported in Exhibit 232, did you perform any other tests the on

56

the coated or uncoated samples for purposes of this litigation?
A. No.
Q. Did Arthrex's attorneys or anyone provide you with any documents that helped you render any opinions expressed in Exhibit Number 232?
A. No.
Q. Did you read any deposition transcripts from this case for purposes of rendering your opinions in Exhibit Number 232?
A. The only thing that I had looked at was back in paragraph five.
Q. Dr. Fenton's report?
A. Yeah, I had seen that but -- I don't specifically remember it -- but I had seen it at the time.
Q. How did you see it?
A. It was sent by Sal.
Q. Other than Dr. Fenton's report, did you receive any other documents from anyone for purposes of rendering opinions in this case?
A. No.
Q. Prior to performing tests reflected in Exhibit Number 232, had you ever performed a tactile feel analysis on a coated and uncoated suture before

57

Arthrex asked you to do it for purposes of this litigation?
A. No.
Q. Have you ever performed a knot tie-down analysis on a coated and uncoated suture before Arthrex asked you to do it for purposes of this litigation?
A. No.
Q. The tactile feel analysis that you performed, as reflected in Exhibit 232, is that a published test?
A. No.
Q. The tactile feel analysis that you performed, as reflected in Exhibit 232, was that a standard test?
A. Not that I'm aware of.
Q. So you are not aware of any publications describing the tactile feel analysis that you performed in Exhibit Number 232?
A. No.
Q. The knot tie-down analysis that you performed, as reflected in Exhibit 232, is that a published test?
A. I would say I'm unaware.
Q. Unaware of what?

A. Unaware if it's a published test. I'm sure there are some industry standard tests that get done on sutures, but I don't specifically know what those tests are.

Q. The knot tie-down analysis that you performed, as reflected in Exhibit 232, is that a standard test?

A. No.

Q. Have you ever used an uncoated suture during surgery?

A. I would think I probably have.

Q. Why do you say that?

A. I would say over the years we've used an awful lot of different types of sutures, and my best guess would be that there are some that don't have a coating or some other treatment.

Q. Can you specifically recall ever using an uncoated suture in a surgical environment?

A. I guess I would answer that by saying I'm uncertain. If we had a list right now of sutures that would be considered uncoated, I probably would say oh, yeah, I've used three or four of those, but I can't give you a specific knowledgable answer.

Q. Do you know of any uncoated sutures that are currently on the market?

A. I think there may be many sutures that don't have coating.

Q. Do you know of any uncoated sutures that are currently on the market?

A. I wouldn't be able to say "I know this is an uncoated suture", no.

Q. Can you specifically name any uncoated suture that you've used in a surgical environment?

A. No.

Q. Moving on to paragraph nine of Exhibit 232, you state: "In March 2006 I received two samples of suture labeled suture A and suture B. Each sample was on a spool and was approximately three meters in length." Do you see that?

A. I do.

Q. Who sent you the two samples you refer to in paragraph nine of Exhibit 232?

A. I believe I received them from a company in California.

Q. Do you know the name of that company?

A. I don't.

Q. Does the name CETR mean anything to you?

A. Only in that -- I think that Sal had mentioned that they had done tests or had been somewhat involved with the suture, but it otherwise

doesn't mean anything to me.

Q. Between February of 2006, the initial conversation you had with Sal, and March 2006 when you had the samples, how many conversations did you have with any Arthrex attorney?

A. Either zero or maybe one to say, hey, the suture is coming and it will be there next week or something.

Q. You just said when Sal mentioned that there would be somebody in California sending you the sutures, did that happen in the initial conversation or did that happen in a conversation after the initial February 2006 conversation?

A. In the initial February 2006, I don't think there was a mention of suture being sent. I think it would be a subsequent that the suture was being sent.

Q. Do you remember anything from the subsequent conversation -- do you remember anything from the conversation after the initial February 2006 conversation but before you received the sutures in March of 2006?

A. Only that there was a conversation about timing of when the suture might get sent or something.

Q. Did you physically -- what physically did

you receive from the California company when you received the two samples?

A. I received a plastic bag with a sort of enlarged spool, if you will, that had some suture on it that said sample A and a similar way for one that said sample B.

Q. Were there two plastic bags each containing one bag of suture?

A. Yes.

Q. Anything else?

A. Packing material.

Q. What was on the spools?

A. Just, you know, a length of suture.

Q. Let me rephrase the question. What markings were on the spools that you received in March 2006?

A. Just sample A, sample B.

Q. Was that handwritten?

A. My recollection would be that it was, but I'm not sure.

Q. Do you know whose handwriting that was?

A. No.

Q. Did it say "Pearsalls" on the spool?

A. I don't remember that.

Q. Other than sample A and sample B, can you

remember any other marking on the spools?
A. No.
Q. Do you know who put the samples on the spools that you received in March 2006?
A. No.
Q. Could it be that there were other markings on the spools other than suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. Certainly there could have been, you know, some marking or name, but I don't remember anything else that would be pertinent.
Q. When you received the samples in March 2006, did you have any indication of whether suture A or suture B was coated or uncoated?
A. No.
Q. So once you received the samples in the two plastic bags on the spools, what did you do next?
A. Took the suture out, cut the suture with just regular scissors to make some lengths, and sort of had an A pile and a B pile.
Q. Where were you when you received the suture samples in March of 2006?
A. I believe they came to my office.
Q. Did you perform the test in Exhibit 232 at

your office or at home?
A. I actually did it at home.
Q. Did you do any tests at the office?
A. No.
Q. So you received the samples in the office and then brought them home?
A. Yes.
Q. Did you cut them at home?
A. Yes.
Q. And then after you cut them, how did you segregate suture A and suture B?
A. I just put all the A's from the one spool in a single pile and the B's in a separate pile.
Q. How long were the lengths of suture when you cut them off the spool?
A. They were roughly a couple of feet.
Q. Was there anybody else present when you performed the tests in Exhibit 232?
A. No.
Q. Was there anybody else present when you cut the samples off the spools?
A. No.
Q. It also says in paragraph nine: I was told by Arthrex's attorney that one sample was coated and that the other sample was uncoated: however, I was

not told which sample was coated and which was uncoated.
Other than the coated versus uncoated distinction, were you told of any other differences between the two samples?
A. No.
Q. Once you cut the sutures off the spools, what did you do with the spools?
A. Ultimately I pitched them.
Q. At home?
A. Uh-huh.
Q. You threw them away?
A. Yes.
Q. What about the plastic bags that were used to hold the suture samples?
A. Same.
Q. You threw them away?
A. Uh-huh.
Q. So you cut five samples from each spool, right?
A. Correct.
Q. So you had five strands of suture A and five strands of suture B each segregated into their own pile, right?
A. Yes.

Q. What did you do next?
A. I spent a little time taking different sutures from one pile or from the other pile and just looked at them, felt them, handled them to see if I could tell much difference between them.
Then I put them around a small hook to be like a suture anchor environment, if you will, and I tied some knots down, some slip knots, to see how it would feel.
Then I wet it, immersed the sutures, and tied again to see if I could tell much of a difference.
Q. You said you spent a little time taking different sutures from one pile and the other and just looked at them, handled them, felt them to see if I could tell much difference between them.
What you just described there, is that the tactile feel analysis that you performed as reflected in Exhibit 232?
A. Yes.
Q. About how long did it take to perform the tactile feel analysis as reflected in Exhibit 232 from the time you cut the sutures until the time you concluded that there was a difference between suture A and suture B??

66

A. Ten, 15 minutes.
Q. About how long did it take to perform the knot tie-down analysis as reflected in Exhibit 232 from the time you cut the sutures off the spools until the time you concluded there was a difference between suture A and suture B?
A. Maybe 45 minutes. Can we stop one second?
MR. FALKE: Sure.
THE VIDEOGRAPHER: Off the record, 4:52.
(Discussion off the record.)
THE VIDEOGRAPHER: On the record, 4:56.
Q. (By Mr. Falke) Can you please describe the tactile field analysis as shown in paragraph 11 of Exhibit 232?
A. Well, it was a very subjective test of taking the suture and running it through the fingertips and pulling it back and forth. Nothing fancy.
Q. Other than running it through your fingertips and pulling it back and forth, did you do anything else in the tactile feel analysis?
A. No.
Q. How many times did you perform the tactile feel analysis in Exhibit 232, paragraph 11?
A. I'm not sure I could give you a specific

67

answer on that from memory. I would say six to eight.
Q. On each --
A. On each sample set.
Q. Okay. On each sample set or on each individual suture in the sample?
A. I did not do each individual suture.
Q. So you did not actually perform a tactile feel analysis on each of the five sutures in suture set A and suture set B?
A. Probably that would be true.
Q. So then you can't say for sure whether all of the five in suture A were generally smoother than the five in suture B, is that right?
A. They all came from the same spool so the properties of one strand should be pretty similar to the properties of the next strand.
So the short answer would be yes, I didn't compare each strand but the strands I felt would be pretty representative coming from the same length.
Q. You can't say for sure that all the five in A were smoother than all five in suture B?
A. Correct.
Q. Prior to performing the tactile feel analysis in Exhibit 232, did you have any preconceived impression of how the coating would affect the feel of

68

the suture?
A. I guess I assumed that a coating would make it smoother.
Q. Anything else?
A. No.
Q. In the tactile feel analysis, which you just described, it sounds like what you described was just in the dry environment, is that correct?
A. That part, yes.
Q. Did you perform the tactile feel analysis in a wet environment as well?
A. No, it was more knot-tying.
Q. So you did not test FiberWire in a wet environment in the tactile feel analysis in Exhibit Number 232?
A. No.
Q. But in paragraph 11 it says: "The difference between the two samples was even more pronounced when they were wet, which is how I'm accustomed to using FiberWire"?
A. Yes. That is, when you are tying knots and you are doing it in the wet environment, then you're feeling the sutures.
Q. Right, but if you look at paragraph 11 in Exhibit 232, paragraph 11 deals with the tactile feel

69

analysis, right?
A. Correct, so what I'm saying on the tactile feel analysis is I'm feeling it in a dry environment where I'm not doing anything with the suture, just feeling it in a dry environment. Then I feel it in the wet environment when I'm tying knots.
Q. So in paragraph eleven when it says "was more pronounced when they were wet which is how I'm accustomed to using FiberWire" that's not true, though, right? You didn't perform --
A. I think the confusion is maybe how I worded this. So when tying knots it's not -- I didn't view it personally as being totally separate of tactile over here and then a tactile over here.
When you are tying the knot, you feel the suture and you are sliding the knot on it. That was part of my assessment when I'm tying the knot. It wasn't just laying it out and feeling it. It's a combination.
Q. How do you know that the samples being wet was more pronounced in the tactile feel analysis if you did not do the tactile feel analysis on a wet suture?
MR. TAMBURO: Objection; asked and answered, mischaracterizes the testimony.

70

A. I'll try to clarify again. I didn't, in my mind, view it as a pure test A/test B. So when you handle suture tying knots and doing things with it, you have a tactile feel. So I didn't -- so that's part of the knot tying. So I didn't segregate it out as two isolated separate things.

Q. So in your report, Exhibit 232, are you making two conclusions based on a conclusion of the tactile feel analysis and a conclusion based on the knot tie-down analysis?

A. I'll try to clarify again. A knot tie-down analysis I view as having a tactile aspect to it as well, you are feeling the suture as you tie it. So I don't view them as totally isolated.

Q. Okay. So how many analyses did you perform as reflected in Exhibit 232?

A. I used all the strands and tied multiple knots on all the strands. So I'm not, I guess, quite sure -- I can't tell you I did 20 knots on each strand or 30, but they were each used for multiple knot tying.

Q. My question might have been unclear. Not how many times did you perform the analysis, but how many different analyses did you do in coming to the conclusions as expressed in Exhibit Number 232?

71

MR. TAMBURO: Objection, vague.

A. I felt the suture and I tied knots with the suture.

Q. But earlier you testified that that's all encompassed in the knot tie-down analysis. So I'm wondering did you do a knot tie-down analysis and that's it and that had two subparts or two different analyses and then come up with a conclusion -- come up with two different conclusions?

MR. TAMBURO: Objection, mischaracterizes the testimony.

A. Again, I'm not trying to characterize in this that these are segregated separate tests, but this was a tactile feel and knot tying. It was a length subjective feel on both of those.

So when you tie knots, you get a tactile feel. So I was making the statement that on the tactile feel, how it feels to me, it felt this way and when I tied knots, it also felt that way. It's sometimes hard to do one without doing the other.

Q. When you were doing -- when you did the tactile feel analysis and the knot tie-down analysis as expressed in Exhibit 232 were you wearing gloves?

A. Not always.

Q. Can you explain the breakdown?

72

A. I tried to try knots partly with gloves to see if I felt that there was a difference and partly without gloves to see if I could feel a difference.

Q. Did using gloves in the tests in Exhibit 232 affect your ability to distinguish between suture A and suture B?

A. I think, clearly, using gloves makes the feel of the suture a little different. I guess I can't answer directly to say if it makes the difference but, yes, it probably makes a difference.

Q. What difference does it make?

A. You are covering your skin with the gloves, so, you know, as you feel suture, your absolute sensation of the suture probably changes some.

Q. Could you have reached the same conclusions you reached in Exhibit 232 if you solely used gloves in performing the tests?

A. I didn't do it that way, so I guess I can't answer that and say yes or no.

Q. Did not using gloves help you to distinguish between suture A and suture B?

A. Potentially, yes.

Q. Did it or -- I'm asking you if, in fact, it did?

73

A. And I'm telling you my answer is it potentially did.

Q. I don't think I understand that. How could it potentially? I mean either it did or didn't, right?

A. No.

MR. TAMBURO: Objection, argumentative.

Q. Why do you say "potentially"?

A. I'm trying to be honest. I did feel without gloves and I know there's a pile A and a pile B, so there is potential that feeling suture without gloves made me feel that A was a little different than B that had I been gloved the entire time, I might not have detected.

Q. So from start to finish then after you cut the suture samples until the time you made your conclusions expressed in Exhibit Number 232, how long was that?

A. I'll give you the same answer: 45 minutes or so.

Q. So the 45 minutes encompassed roughly ten minutes you spent on the tactile feel analysis?

A. No.

Q. So 45 minutes plus ten minutes or just 45 minutes?

A. I would say it was probably 45 minutes plus ten minutes.
Q. Did you tie knots in each of the individual five sutures from suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. Yes.
Q. After you performed the tactile feel analysis and knot tie-down, as reflected in Exhibit 232, what did you do with the sutures that you tested?
A. I pitched them with the spools.
Q. You threw them out?
A. Yes.
Q. Did counsel ever instruct you to not throw away the samples?
A. No.
Q. Did counsel give you any instructions at all what to do with the samples once you performed the tests on them?
A. No.
Q. Did you throw them away at home or at the office?
A. At home.
Q. And then once you completed the tactile feel analysis and knot tie-down analysis and once you threw away the sutures, what did you do next?
A. Well, as it regards this, I sent an e-mail to Sal and said here's what I thought.
Q. Do you have a copy of that e-mail?
A. Nope.
Q. What did you do with the e-mail that you sent to Sal after you concluded the tests?
A. What did I do with the e-mail? I didn't do anything with the e-mail. I hit "send".
Q. It's still on your computer?
A. I would doubt it's on the computer. I mean, just due to the volume, they don't keep three months or four months or whatever.
Q. Did you send it from work or home, the e-mail?
A. I don't know for sure.
Q. You don't know for sure?
A. No.
Q. Did you delete the e-mail you sent to Sal after you finished performing the tests?
A. I'm not sure I understand deleting the e-mail. I sent him an e-mail. I didn't purposefully delete any e-mail.
Q. Do you use Microsoft Outlook for your e-mails?

A. No.
Q. What program do you use for your e-mails?
A. At home it's a Comcast e-mail and then here it's a Group-Wise.
Q. But do you use -- what e-mailing system do you use at home? Is it AOL or Lotus Notes or Microsoft Outlook or a Yahoo account?
A. It's a Comcast.
Q. That's done on a personal computer?
A. Yes.
Q. What about in the office? What kind of e-mailing system do you use?
A. We call it Group-Wise.
Q. Is the e-mail account you have at home different than the one you have at the office?
A. Uh-huh.
Q. Did you look for the e-mail in response to the subpoena, Exhibit Number 231?
A. Yes. The e-mail -- I mean, my awareness of the e-mails is that they go back two or three weeks or so and then after that they just go into cyberspace.
Q. So you did not look for the e-mail in response to the subpoena, Exhibit 231?
A. No, because that was like three months ago.
Q. When you say the e-mails go back two or three weeks and then go into cyberspace, you are referring to work e-mail or your home e-mail?
A. Well, primarily, I guess I'm referring to the work one. I don't use the home as much. So I don't. . .
Q. Do you remember what the e-mail said that you wrote to Sal after you performed the tests in Exhibit 232?
A. Pretty much what's in here. I just said, you know, sample A to me felt this way compared to sample B.
Q. Felt -- what word did you use to describe how suture A felt in relationship to suture B?
A. I don't remember specifically but, I mean, I probably used a word like "smoother".
Q. But you are not sure?
A. I'm not sure of the word.
Q. Did Sal send an e-mail back to you once you sent him the e-mail after completing the tests in Exhibit 232?
A. Not that I remember specifically.
Q. When was the next time you spoke to Sal after sending the e-mail on which you completed the

tests in Exhibit Number 232?
A. Oh, boy. I don't remember specifically.
Q. Do you remember what day you completed the tests in Exhibit 232?
A. No.
Q. Did you take any notes while doing the tests in Exhibit 232?
A. I did not.
Q. Do you remember how long -- what the time period was between completion of this report and completion of the tests?
A. I don't honestly remember specifically. It seems to me that it was a shorter time because of time demands on the case.
Q. Like two weeks or a week?
A. Yeah. I'll guess in that range. I'm not sure.
Q. So then once you sent the e-mail to Sal saying that you completed the tests and giving the conclusions you came to, what happened next?
A. Probably nothing until Sal contacted me and said, you know, there's a report that we need to do on this, and, you know, we need a CV and we need other information and stuff like that.
Q. What happened next?

A. We had a couple conversations about what would go in the report. He e-mailed a report, it had a few blanks, I filled in the blanks and -- you know, again, like I said, I don't remember e-mailing or whether I picked up the phone or talked to him and had completed that part of it and then he sent a final draft.
Q. Okay. You said you had a couple of conversations about what would go into the report. Do you know how many conversations you had discussing what the report would say?
A. No.
Q. Do you know how the length -- the total length of those conversations about what would go into the report?
A. No. They weren't lengthy.
Q. An hour?
A. I don't even think that much.
Q. Half hour?
A. Yeah, maybe.
Q. Then you talked to Sal after you sent him the e-mail with your conclusions, you had a couple of phone conversations that lasted generally 30 minutes and then Sal sent you a draft of the report; is that right?

A. I think so.
Q. And then you made some changes to the draft that Sal sent you, right?
A. Yes.
Q. And then you sent it back to Sal or you had a phone conversation with Sal, is that right?
A. Yes.
Q. And then did Sal send you another draft of the report after that conversation?
A. Yeah.
Q. And then what happened then?
A. My recollection would be that, you know, I called him up and said it seems okay to me, and I signed it. And, again, I don't specifically remember how he got it back.
Q. So it sounds like that there was at least one initial draft of the report, you made changes to it, and then Sal incorporated the changes, he sent it back to you, and then you signed off on it; is that right?
A. I think that's fair, yes.
Q. In paragraph 15 of your report, it says that within the past four years you've testified as an expert at deposition in one other case; do you see that?

A. Yes.
Q. What case was that?
A. It was a malpractice case.
Q. A medical malpractice case?
A. Yes.
Q. What role did you serve as an expert in that case?
A. I was giving an opinion for the orthopedic surgeon who was being sued in the case.
Q. The defendant?
A. Yes.
Q. Was that Lonnie Paulos?
A. That was.
Q. Just generally, can you just describe the substance of that opinion? I don't want you to divulge any confidentiality, but just --
A. Well, the substance of the opinion was that I didn't feel that he had committed malpractice.
It was primarily an anesthetic risk case and he had been the person operating, so he was included in the lawsuit.
Q. Was Dr. Simon Finger the anesthesiologist?
A. I'm pretty sure that's correct.
MR. FALKE: Let's take a break.
THE VIDEOGRAPHER: Off the record, 5:20.

(Brief recess.)

THE VIDEOGRAPHER: Back on the record on record 5:38.

Q. (By Mr. Falke) Dr. Burks, can you explain the knot tie-down analysis that you conducted as reflected in Exhibit 232, paragraph 12?

A. It was taking a strand, tying a knot on it, sliding the knot down and then putting another knot/half hitch, whatever you want to describe it, and sliding it down.

Q. What did you tie the suture samples on?

A. A hook.

Q. What type of hook was it?

A. Just a simple sort of brass hook.

Q. Did you use the same knot configuration for each comparison?

A. I used the same knots for the different groups, but I varied knots to see how different knots might feel.

Q. But for each knot that you tied on suture B, you did that same knot on suture A?

A. Right, right.

Q. About how many knots did you tie in total in the know tie-down analysis for each suture set, generally?

MR. TAMBURO: Objection, vague.

A. When you say suture set, you mean the group of sutures or the individual strand?

Q. The set of five.

A. Okay.

Q. So as an example, if you did 30 total knots is that 15 per suture A and suture B? Let me rephrase the question or repeat the question. About how many knots did you tie in total for each suture set when you did the knot tie-down analysis?

A. I think it would be, again, hard to give you a specific number. I'm not trying to be vague, it's just that when you say a knot, for example, I'm trying to say that I might throw a half hitch down which isn't technically a complete knot, and then I might throw another half hitch, so there might be multiple half hitches that you could consider one knot or you could consider it 20 throws and 20 knots.

Q. Let me try to help you out there then. How many comparisons then did you do in the knot tie-down analysis between suture A and suture B?

MR. TAMBURO: Objection, vague.

Q. Do you understand that?

A. I can tell you what I did and . . .

Q. Please.

A. I mean, I took each strand from each set and I tied multiple knots, if you will, in each strand so each strand may have had 20 throws in it and. . .

Q. So does that mean then you did five comparisons? You did a knot configuration for each of the suture samples?

MR. TAMBURO: Objection; mischaracterizes the testimony, asked and answered.

A. I guess I'm trying to go with you. I'm just not sure what you. . .

Q. When you say "comparisons", I mean, regardless of the knot configurations or how many particular knots were on the one suture, you compared that configuration, whatever it is, to the other suture set, right?

A. Correct.

Q. How many times did you do that?

MR. TAMBURO: Objection, vague.

A. I guess one would say that's five. So the five strands in one set got compared to the five strands in the other set.

Q. Right. Did you wet the suture when you did the knot tie-down analysis?

A. Yes.

Q. How did you wet the sutures?

A. With tap water.

Q. Can you explain that?

A. Sure, I just filled a glass with water and put the suture down in it and then tied the knots.

Q. Did you wet them one at a time?

A. Yes.

Q. How long did the suture stay submerged in water?

A. Briefly. Three or four seconds.

Q. But the same amount of time in the water for each suture?

A. Yes.

Q. Do you know if the sutures absorb water when they're wet?

A. No.

Q. You don't know?

A. No.

Q. Were each of the -- you come to the conclusion in paragraph number 12 of Exhibit 232 that when suture A -- there was less friction when sliding the knot on the sample labeled suture A as compared with sample labeled B. Was that true for all five suture samples?

A. That was a sum feeling on my part. So it might not be fair to say it's true on every strand but

it was my overall take from looking at them.
Q. Do you remember how many -- strike that.
Does a suture that has less friction when sliding that knot mean that the suture has better knot tie-down performance?
A. Not necessarily.
Q. Why?
A. Well, if you envision a perfectly smooth suture, for example, if you slide a knot it might slide very easily but it might also tend to not hold as well because there's not as much inherent friction in it.
Q. Does a smoother suture mean it has better tactile feel than a suture that is not as smooth?
A. I would say no, I don't know that I'd say it's a better tactile feel.
Q. Why did you use a surgeon's knot when you did the knot tie-down analysis in Exhibit 232?
A. I think what I would do is say that -- again, maybe my critique of the verbiage would be at fault. So I guess I wouldn't -- you know, we talked earlier about what a surgeon's knot is.
Q. Uh-huh?
A. And I probably didn't focus on it enough to say that they're not necessarily surgeons' knots as

I described them.
Q. Okay, so why did you use the particular knots, then, that you used in the knot tie-down analysis?
A. I just tried to reproduce what I do in the operating room.
Q. In paragraph 11 in Exhibit 232 you state that suture A generally felt smoother than suture B. What do you mean by "generally"?
A. The differences between the sutures were subtle. I mean, they were not sharp, distinct. So I'm meaning that in comparing them, my take was that it was generally smoother.
Q. Were there any of the sutures in the tactile feel analysis where you couldn't tell the difference between suture A and suture B?
A. It was not my intent at the time in looking at the sutures to compare each strand side to side. My intent was to look at sort of spool A and spool B. So it was to get a feel of, in general, how do they feel between the two.
So I didn't take a strand and say is this one different? And is this one different? And go down through that five times, because I felt it was all the same suture.

Q. But were there any where you couldn't tell a difference? I mean, it was pretty close?
A. Sure, it was pretty close.
Q. Let me rephrase. Were there any where you couldn't tell the difference between suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. I don't remember specifically having ones that I would say I clearly feel a difference on this one and I clearly don't on the next one. It was a general feel of all of them.
Q. Dr. Burks, how would you describe your relationship with Ethicon?
A. I guess none.
Q. None? So you would say that you have a closer relationship with Arthrex?
A. Yes.
Q. What about could you describe your relationship with DePuy Mitek?
A. I have been a consultant with DePuy Mitek. Just this week I was helping on an educational course for DePuy Mitek reps. But I've had no product or anything like that with DePuy Mitek.
Q. You mean development product work?

A. Yes.
Q. What was the educational course this last week that you helped with DePuy Mitek?
A. It was educating reps who go into the operating room and, you know, are helping surgeons with their materials, sutures, implants, what not, and how to handle the operating room environment, be appropriate and be helpful.
Q. The course was not on a particular DePuy Mitek technique or anything like that, it was --
A. It was not focused on a particular product but it was focused on helping reps better sell DePuy Mitek products.
Q. By being more professional in the operating room?
A. Correct.
Q. Is this the first time you have done that for DePuy Mitek?
A. This is the second.
Q. Other than those two courses, have you consulted with DePuy Mitek in any other courses?
A. Yes.
Q. What are those?
A. There was an educational course in Chicago and you are going to say when and I'm going to guess

90

four years ago. It was a cadaver course where they were doing DePuy Mitek products and they asked me to come give a couple of talks and help in the lab using those products with the doctors who were there.
Q. Do you remember what those products were?
A. Not specifically. They were suture anchors, suture passing instruments, but I don't remember a specific product.
Q. Are you a consumer of DePuy Mitek products?
A. Sure.
Q. What DePuy Mitek products do you use?
A. Well, I mentioned earlier I use OrthoCord. I use some DePuy Mitek anchors. They make an electric cautery unit that we use, in every case we use electric cautery.
They have some suture-passing instruments that we use. I use one of their drill guides and fixation sets for ACL surgery.
Q. When you do an ACL fixation, what product do you use?
A. It depends on the type of ACL that we're doing. If I use a bone/tendon/bone graft which is a common graft, on the femoral side, I fix it with a DePuy Mitek device which is a couple of absorbable

91

pins, and on the tibial side I fix it with either a DePuy Mitek screw or a screw from a different company depending on upon quality.
On the hamstring, I typically on the femoral side use a Smith and Nephew product --
Q. EndoButton?
A. EndoButton. On the tibial side I typically use a Milagro screw and frequently for the post use that Arthrex screw.
Q. When you say hamstring, that's soft tissue?
A. Correct.
Q. Semitendonosis?
A. Very good.
MR. TAMBURO: We're all half doctors here.
MR. FALKE: Let's take a break.
THE VIDEOGRAPHER: Off the record, 5:54.
(Brief recess.)
THE VIDEOGRAPHER: On the record, 6:02.
Q. (By Mr. Falke) Dr. Burks, I'm going to hand you DePuy Mitek Exhibit 286, DePuy Mitek Exhibit 284 and DePuy Mitek 285. These are FiberWire samples that were produced to us from Pearsalls who is a company that makes FiberWire for Arthrex.
I covered up on those exhibits the

92

manufacturing state that those sutures have gone through. And I'm wondering if you can look at those, analyze them, do whatever you have to do, but tell me which ones are coated and which ones are not coated, if any?
A. So these are three separate types of suture?
Q. They're three different sutures. Well, I'm going to take that back. I don't know if they're three different sutures.
MR. TAMBURO: You are not sure what they are.
MR. FALKE: We know what they are, yeah. I mean, based on Pearsalls' representations of what they are. If you need to cut them and get you a glass of water, if you want to wet them.
MR. TAMBURO: Are they in the same form in which they were produced?
MR. FALKE: Yes, we did not alter them.
MR. TAMBURO: Do we have Bates numbers?
Q. Slow down. Just for the record, so the record is clear, what did you just do, Dr. Burks?
A. I just opened the suture that was in the bag.
Q. What Exhibit Number is that?

93

A. That is 286.
Q. You cut a piece off of the suture in Exhibit 286?
A. Right.
Q. And --
MR. TAMBURO: There's no Bates numbers on these?
MR. FALKE: There were no Bates numbers.
Q. Would you put that on the suture you cut from Exhibit 286 and mark with a pen Exhibit 286. Now, can you explain what you are doing now, Dr. Burks? First, can you put the suture that you took out of 286 back in the bag?
A. (Witness complies.)
Q. Thank you, and then proceed. Can you explain for the record what you are doing now?
A. I'm opening 285.
Q. You are cutting suture sample from Exhibit 285, right?
A. Yes.
Q. Could you please mark with the tape Exhibit 285 that you've cut? Proceed. Can you state what for the record what you are doing now?
A. I'm opening number 284.
Q. And cutting a suture from Exhibit 284?

A. Yes.
Q. And now you are going to mark the suture sample that you took from Exhibit 284 with a flag?
A. Correct.
Q. Can you hand me the original sample sets back?
A. (Witness complies.)
Q. Also, I'm going to hand you DePuy Mitek Exhibit 234 which is a chart I'd like you to fill out if you could, please, and under the suture column put the numbers corresponding to the suture samples you've just cut, just 284, 285 and 286?
A. Fair enough?
Q. Fair enough.
A. Have we got a while?
Q. However long it takes you.
MR. TAMBURO: Are you representing that one of them is coated, one of them is not coated?
MR. FALKE: I'm not making any representations. They could all be coated, they could all be uncoated, could be a mix?
A. Can I use your notebook?
Q. Of course. What do you need?
A. I was going to use one of those metal rings.

Q. Sure. First, can you do a tactile feel analysis on it? Can you tell the difference?
A. Kind of -- like I said, when you tie knots you combine that together.
Q. Can you explain what you are doing now?
A. I don't want to knock your little deal off, you know? I'm just getting a sense for how it slides and trying to put down a couple of throws.
Q. Which Exhibit Number are you working on?
A. I'm on 285.
Q. Okay. What type of knots are you throwing?
A. Half hitches.
Q. Now, can you explain what you are doing, Dr. Burks?
A. Same thing.
Q. With which exhibit?
A. 286.
Q. Are you doing the same thing you did with the previous one?
A. Yes.
Q. Same knot configurations?
A. Uh-huh.
Q. Can you tell a difference between the first two sutures, Dr. Burks, Exhibit 285 and --
A. 286.

Q. And 286? Can you explain for the record please what you are doing now, Dr. Burks?
A. I'm tying 284.
(Discussion off the record.)
A. Okay. So where is my little sheet here?
Q. Based on what you've done so far, Dr. Burks, can you tell any difference between the sutures?
A. I feel like I do feel a difference.
Q. Okay. How would you describe that difference?
A. Well, I would say at the moment 285 seems a little smoother to me than 284. So I would say 285 is coated and 284 isn't coated.
Q. How sure are you of that?
A. I would not put my children's lives on it, but given the subjective feel.
Q. Is it a subtle difference?
A. It's a subtle difference.
Q. Can you explain, Dr. Burks, what you are doing now?
A. Just throwing knots. I would say 286 seems coated as well.
Q. If you had gloves on right now, would that change the confidence level you have in determining

whether those are coated or uncoated sutures?
MR. TAMBURO: Objection, calls for speculation.
A. I think gloves can make a difference, yeah.
Q. How do they make a difference? The difference between the sutures is more subtle, right, with gloves because you don't have the contact like you described earlier with the skin?
A. Yeah. Again, this is obviously a very subjective feel test. Some of that feel comes from how the suture feels and some of it comes from how you feel when you slide a knot. So we're not talking rocks and water as far as differences and so. . .
Q. How would you qualify the difference that you just observed, based on your test?
A. When you say "qualify" are you asking for like an amount?
Q. How would you characterize the difference between the sutures?
A. Well the difference is, I think, subtle and there's no doubt in my mind that I could line up, you know, a hundred sutures and have error where I would say, you know, I think this one is one way or the other and make a mistake.

So there's certainly not enough difference to clearly say that I know every time exactly how that feels.

Q. Okay. Could you just initial, please, the chart that you did?

A. This right here?

Q. Yes.

A. Okay.

Q. And put the date.

A. (Witness complies.)

Q. Okay. For the record, I have to mark the exhibits, the sutures that you tied onto my binder. Can you untie those?

A. I can just open the binder.

Q. How confident were you that 286 was coated?

MR. TAMBURO: Objection, vague.

A. I guess I've said that differences are subtle. So I'm going by a subjective feel. So I feel like there's a difference. Am I going to bet a lot of money on it? No, but that's my take.

MR. FALKE: Okay. For the record I'm going to mark the suture that Dr. Burks tested with Exhibit 235 -- I'm going to state that over again.

For the record, I'm going to mark with

Exhibit 235 the suture Exhibit 284 that Dr. Burks just tested, and I'm going to mark Dr. Burks' tested suture 286 with DePuy Mitek Exhibit 236, and I'm going to mark Dr. Burks' tested suture 285 with DePuy Mitek Exhibit 237.

I have no further questions.

EXAMINATION

BY MR. TAMBURO:

Q. Dr. Burks, there was some discussion about work you had performed on behalf of DePuy Mitek; do you recall that?

A. Yes.

Q. Were you compensated by DePuy Mitek for the work you performed?

A. Yes.

MR. TAMBURO: I have no further questions.

MR. FALKE: Okay, thank you for your time.

THE VIDEOGRAPHER: End of deposition, 6:18.

-O-

Deponent's Certificate

I, ROBERT T. BURKS, M.D., deponent herein, do hereby certify and declare the within and foregoing transcription to be my deposition in said action taken on June 7, 2006; that I have read, corrected, and do hereby affix my signature to said deposition.

DATED this _____ day of _______________, 2006.

____

Deponent

)
STATE OF UTAH) ss.
)

SUBSCRIBED AND SWORN to before me this _____ day of ____________________, 2006.

____

Notary Public residing in

____

My Commission Expires:

____

Reporter's Certificate

State of Utah)
County of Salt Lake)

I, Denise Kirk, Certified Shorthand Reporter, Registered Professional Reporter, and Notary Public for the State of Utah, do hereby certify:

THAT the foregoing proceedings were taken before me at the time and place set forth herein; that the witness was duly sworn to tell the truth, the whole truth, and nothing but the truth; and that the proceedings were taken down by me in shorthand and thereafter transcribed into typewriting under my direction and supervision;

THAT the foregoing pages contain a true and correct transcription of my said shorthand notes so taken.

IN WITNESS WHEREOF, I have subscribed my name and affixed my seal this 11th day of June, 2006.

____

DENISE KIRK, CSR/RPR

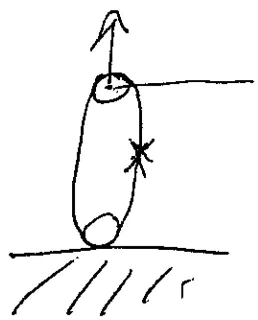
My commission expires:
August 30, 2006

BROOKSTEIN DECLARATION
EXHIBIT 24

DEPUY MITEK
EXHIBIT 113
04cv12457

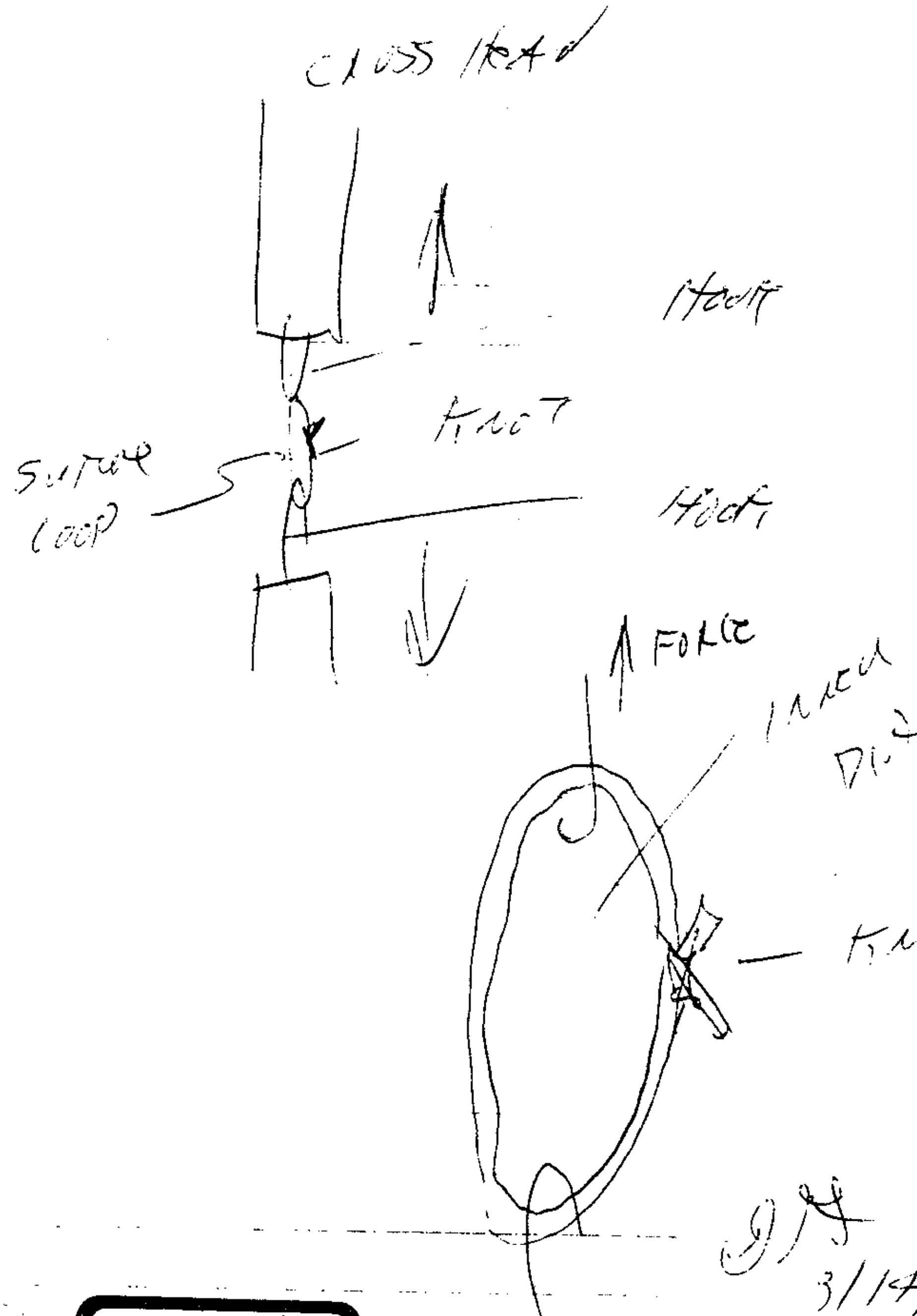
Knot Security

~~Side~~
Front View



A. H. 09/15/05

BROOKSTEIN DECLARATION
EXHIBIT 25



3/14/06

BROOKSTEIN DECLARATION
EXHIBIT 26

EXHIBIT
D. Ruy Mitek #78
DONOVAN Court Reporting

78

Arthrex®

February 28, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation 510(k)
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: 510(k) Premarket Notification: **Arthrex FiberWIRE™**

Dear Ladies and Gentlemen:

This is to notify you of the intention of **Arthrex, Inc.** to market the above referenced medical device in the United States. We are seeking permission to market the device for the following intended use: general soft tissue approximation, and/or ligation.

This submission is submitted in duplicate and is provided to comply with Section 510(k) Premarket Notification of the Federal Food, Drug and Cosmetic Act in conformance with CFR Title 21, Part 807 Subpart E. This submission includes provisions related to 510(k)'s in the Safe Medical Devices Act of 1990 (SMDA), Public Law 101-629.

Arthrex, Inc. regards the referenced Arthrex FiberWIRE™ to be 'substantially equivalent' as defined for use under the Act to devices of the same type that were in commercial distribution prior to May 28, 1976, or equivalent. The enclosed information addresses the requirements of the Act pertaining to this 510(k) Notification.

We request that the Food and Drug Administration hold as commercial confidential information the intent to market this device for this indication to the fullest extent as authorized by law.

Specific information is submitted as listed in the TABLE OF CONTENTS, Appendix 1 through Appendix 8.

Thank you for your assistance in this matter.

Sincerely,

for

L. Brette Masino
Regulatory Affairs

CONFIDENTIAL - NON-PATENT
PROSECUTION COUNSEL
ONLY

ARM 001888

Arthrex FiberWIRE™ Braided Polyblend Suture
Non Absorbable Surgical Suture, USP & EP Conformance

Description

Arthrex FiberWIRE™ is a blend of long chain polyesters braided and sterilized for surgical use. Arthrex FiberWIRE™ is coated with a silica reinforced polydimethyisiloxane. The coating acts as a lubricant for suture sliding and knot tying and ease of passing the suture through tissue.

Arthrex FiberWIRE™ is available in non-dyed (white) or dyed (D & C Blue No. 6) and exceeds USP and EP standards for diameter, knot strength and straight pull strength.

Indications

Arthrex FiberWIRE™ is indicated for use in soft tissue approximation and or ligation.

Actions

Arthrex FiberWIRE™ elicits minimal acute inflammatory reaction in tissue, as evidenced by in vivo testing. Polyester suture has been shown to become encapsulated by fibrous connective tissue during healing. The polyester suture, Dye (D&C Blue No. 6), and di-peroxide silicone oil (coating) are pharmacologically inactive.

Contraindications

None Known

Warnings

Users should be familiar with surgical procedures and techniques for using non-absorbable suture including wound closure and knot tying.

Do not resterilize. Do not use suture form previously opened or damaged packages.

Precautions

Care should be taken when handling braided suture to prevent damage to the individual filaments from abrasion or crimping which could effect the mechanical characteristics of the suture. Do not expose to heat. Assure all knots have been secured using accepted surgical knot tying techniques. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

TRAVEL TRANSCRIPT

DePUY MITEK, INC.,)
Plaintiffs,)
)
vs.)
)
ARTHREX, INC., a Delaware)
corporation,)
Defendants.)

DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Courtyard Marriott, 423 Speen Street, Natick, Massachusetts, on Thursday, 26 January, 2006, commencing at 10:44 a.m.

Page 46

MR. BONELLA: Answer that yes or no.
A. Yes.
Q. Did the general subject matter concern the process of obtaining a patent for that work?
MR. BONELLA: You can answer that yes or no or to the extent you remember.
A. The process -- clarification: The process of obtaining a patent in general or this patent?
Q. This patent. This patent.
A. No.
Q. And again, I want to make sure that you understand the question that -- when I mean that the steps of applying for a patent and the steps of prosecuting a patent --
A. No.
Q. Didn't get into that.
A. (Nods.)
Q. Was there any other -- in the general subject matter, was there any other general subject matter that you discussed other than your work that you did that led up to the patent?
A. No.
Q. Other than that one meeting that you had with Mr. -- that meeting was with Mr. Bonella?
A. Yes, and one of Mr. Bonella's associates.

Page 47

Q. All right. Who else was there?
A. It was a woman. I don't remember her name.
Q. Was it Ms. Malinoski?
A. Do you know her first name?
Q. Lynn.
A. Lynn, yes.
Q. Was anyone else there other than the three of you?
A. No.
Q. Other than that meeting, was there -- have you had any discussions with anyone associated with the Johnson & Johnson Company about this litigation?
A. No.
Q. Other than that meeting, have you had any discussions with anyone associated with Johnson & Johnson Company concerning the work you did that led to the Hunter patent?
A. No.
Q. In connection with your preparation for your deposition today, other than -- did you do anything other than review the Hunter patent and the meeting you had with Mr. Bonella yesterday?
A. I did no other activities. Only those two

Page 48

activities.
Q. In connection with your deposition today or in preparation for your deposition today -- other than logistics -- have you had any discussions with anyone associated with any Johnson & Johnson Company for purposes of preparing for your deposition?
A. No.
Q. While you were -- I want to ask questions about the -- particularly the time period of 1988 to 1992 when you were at Ethicon. Let me ask this first: Once you left Ethicon in '92, did you have any communications with the lawyers who were prosecuting the application that led to the 446 patent, Hunter patent?
MR. BONELLA: You can answer that yes or no.
A. Yes.
Q. Okay. You did. Okay. Were those communications oral or just in writing or both?
A. My recollection were status updates of -- from the attorney --
MR. BONELLA: Again, don't disclose the substance of the communications. That is privileged because it's between an attorney and

Page 49

you.
THE WITNESS: Okay.
A. So --
MR. BONELLA: The question was --
A. Oral or written? My recollection, were oral; possibility there was e-mail status, but --
Q. Were any of the communications that you recall -- were they substantive about issues involved -- that had arisen during the course of the prosecution, or were they merely just, Here's where things stand?
MR. BONELLA: You can answer that yes or no or -- if it's a yes-or-no question. You can answer it -- were there -- the question is, "Were any of the communications that you recall, were they substantive about issues involved that had arisen during the course of the prosecution or were they merely just Here's where things stand." You can answer that question there were substantive discussions, or they were just merely about where things stand.
THE WITNESS: Can I ask -- can I ask yourself, this -- to me this would be attorney/client discussions.
MR. BONELLA: Right. That's why --

Page 102

sutures had to offer, and from an alloying viewpoint, it was a place that you could potentially see the most impact in your first set of experiments, so --

Q. Did you have two different classifications for these two different fibers that you were going to be mixing together?

A. Not at that point. At that point we were talking generically about the advantages of making a composite or alloying.

Q. But were you talking about one group would give one property, and one group would give another property?

A. In some instances, yes.

Q. And how would you characterize the two groups?

MR. BONELLA: Object to form.

A. Well, at that stage -- at that stage, is the question?

Q. Well, let's start with that stage.

A. At that stage, again, we were looking -- we were thinking -- we were envisioning something much broader than just, for example, PE -- Teflon, PTFE, and PET, which we were -- maybe I could take a step back. The environment at the time was we --

Page 103

Ethicon had multiple development programs going, some of which were to make a product that were -- had better properties than silk, and silk has really good handling properties. Some of them had to do with higher strength sutures. Some of them had to do with different biologic profiles in terms of strength retention over time. And the initial discussions were how can we address those types of problems with a combination of fiber types.

So, the initial conversations -- and one of the avenues that came out of that was this maybe opportunity to have a suture that has strength better than silk, but pliability like silk. So, that was one of them.

Q. Okay.

A. And that was one that Al and Art had considered in the past. Again, I'm not clear how far they took that in the past, but they at least considered that. And that was one that we elected to pursue earlier than later, because we had the materials, essentially. We thought it was good opportunity.

Q. So, if I understand your testimony -- at least at the very beginning stage you wanted something that was stronger than silk but handled

Page 104

as well as silk, is that --

A. That was certainly one of the embodiments we were going after.

Q. As the -- as the project -- as the project progressed and as you applied for a patent, is it correct that you were trying to get something that handled better than a homogenous braid but didn't lose strength -- appreciably lose strength from the conventional homogenous braid?

A. The overall project, yeah, I think that was -- that would be a fair assessment of the objective of the overall project.

Q. All right. And the conventional homogenous braid that you were talking about that you wanted to not lose appreciative strength then was Ethibond, is that correct?

A. Right. Ethibond -- well, Ethibond, you know, had good strength, but maybe not as good handling properties as silk,.

Q. Right.

A. Silk had lower strength, good handle properties, and again, one of the concepts was we -- maybe we could get the best of both.

Q. All right. But as you applied for the 446 patent, was it the object there to have something

Page 105

that would -- you weren't trying to make something stronger than Ethibond, correct?

MR. BONELLA: Object to form.

A. No, I can't say that we were trying to make anything stronger than Ethibond. We were looking at this as a technology that could improve -- that could offer properties outside of what the current ones -- so, I mean, could be a potential of blending polyester or something else.

Q. I'm talking about the patent now, as you applied for the patent. I mean, if I didn't make that question clear, I apologize. And so, maybe we should go back to Exhibit 10.

Was it an object of Exhibit 10 -- of the patent, as opposed to the work now --

A. Right.

Q. -- was it an object of the patent to try and produce a suture stronger than Ethibond?

A. (Witness reviews document.) I would say since we're clearly looking at aromids, I would say the answer was yes.

Q. And that was by using an aromid?

MR. BONELLA: Object to form.

A. No. That would be one way of doing it.

Q. Is there anything --

A. We were certainly looking at fiber. We were certainly considering fibers that offer higher tensile strength than -- than strictly PET.
Q. And that was the aromids?
MR. BONELLA: Object to form.
A. That was one of -- that was one example.
Q. Is there anything else?
MR. BONELLA: In the patent?
MR. SABER: Yes, sir.
MR. BONELLA: If you want to read the patent, read the patent. Object to form.
A. Well, the patent describes generic classes of polymers, and the high strength aspect of it has more to do with how those polymers were processed. So, any of those polymers that are listed, you know, could be processed in a high strength form or a medium-strength form or a low-strength form.
Q. When you're saying, "these," which ones are you talking about?
A. I'm referring to the polymers listed in the claims.
Q. All of them?
A. All of those can be processed to get a range of low, medium, or relatively high strength.
Q. All right. Let's look at the

specification, if we could.
A. Okay.
Q. Could you look at Column 4, please. Yes. The paragraph that starts at Line 33.
A. Yes.
Q. Is that paragraph disclosing the polymers which are to act as strength --
MR. BONELLA: Object --
Q. -- to provide improved strength to the braid?
MR. BONELLA: Object to form.
A. (Witness reviews document.) I'm sorry. Could you repeat the question.
Q. Yeah.
MR. SABER: Could you read it back, please.
(Question read back.)
MR. BONELLA: Object to form.
Q. Let me rephrase that. Does that paragraph provide suggested polymers to provide improved strength to the braid?
MR. BONELLA: Object to form.
A. That paragraph describes two sets of -- that describes "Lubricating yarns in the first set --"

Q. Right, in the first set.
A. Right.
Q. "-- that are mechanically blended with yarns of the second set, which act to provide improved strength to the heterogeneous braid." Isn't that talking about the second set, providing "improved strength to the heterogeneous braid"?
A. Yeah, within the context of this paragraph. But once again, PET, for example, could be, you know, could be in a -- in a low strength or medium strength or a high strength.
Q. I'm talking about what's being -- what's being explained in this paragraph.
A. Okay.
Q. Is this -- isn't it true that this paragraph is explaining that the -- that the yarns from the second set are there to provide improved strength to the braid?
MR. BONELLA: Object to form.
A. My read of this is that in this particular embodiment, the second set would be offering strength.
Q. And that's the only yarns that are specifically mentioned are PET, nylon, and aromids, is that correct?

MR. BONELLA: Object to form.
A. Those --
Q. As providing the strength.
A. Those are the only --
MR. BONELLA: Object to form.
A. -- ones mentioned.
Q. In that paragraph?
A. As far -- yes.
Q. Is there any other mention in this patent -- specific mention of any other yarn there to provide strength?
MR. BONELLA: In the patent?
MR. SABER: Yes, sir.
MR. BONELLA: If he needs to read the patent, read the entire patent to answer the question then.
A. Are there any other fibers mentioned --
Q. Any other yarns mentioned to provide strength --
A. I would say.
Q. -- to the --
A. Any of the polymers that we mentioned could be the strength.
Q. Could you tell me where it says that. I want to know exactly what you're relying upon in

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS
DAY II

TRAVEL TRANSCRIPT

DePUY MITEK, INC., Plaintiffs,	)
vs.	)
ARTHREX, INC., a Delaware corporation, Defendants.	)

CONTINUED DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Hilton Hotel, 25 Allied Drive, Dedham, Massachusetts, on Friday, 3 February, 2006, commencing at 9:06 a.m.

Page 262

embodiments you described to the attorneys during the -- during the period of -- up to the filing of the application?
MR. BONELLA: That's a yes or no. You do recall it or you don't. Don't go into the substance.
A. No.
Q. You don't recall.
A. (Witness nods.)
Q. When did -- when did you first have contact with the patent attorneys -- strike that. Was contact with the patent attorneys the first thing that happened in your involvement that led up to the filing of the application?
A. Yes.
Q. When did that first occur?
A. I have no recollection of the actual date.
Q. Can you give me any approximation? And you can use -- if you want to use the filing date as a reference, go ahead.
A. There's -- I'm sorry. Could you repeat the question.
(Question read back.)
A. I'm sorry. Sometime after March 1990, but I don't have it.

Page 263

Q. Can you give me any estimations between March of 1990 and February 19th of 1992 of when your contacts with the attorneys began?
A. I'd just be guessing. No.
Q. Okay. Can you -- can you give me any way of narrowing that time frame down.
MR. BONELLA: Objection. Asked and answered numerous times.
A. Just too many going on. Too long ago.
Q. Okay. You mentioned Mr. Goodwin and Mr. Skula. Could you describe to me, if you can, kind of what your understanding of their respective roles were in the preparation of the application.
A. My understanding was they were J&J patent attorneys assigned to Ethicon that would work with inventors to actually draft patent applications.
Q. Do you have any understanding of the difference in the role between Mr. Goodwin and Mr. Skula?
A. My understanding was Mr. Skula replaced Mr. Goodwin at some time, but I don't -- I thought they had the same role.
Q. Okay. You believe Mr. Skula replaced Mr. Goodwin?
A. I have some recollection of Mr. Goodwin

Page 264

moving on to different responsibilities and Mr. Skula picking up on this. But I -- I have to say I had several applications going, and I don't know if I'm remembering this one.
Q. All right. That change in roles, do you know if that was before the application was filed or after?
A. No, I don't.
Q. You just don't recall?
A. I just don't recall.
Q. And I apologize if I asked you, do you recall Mr. Woodrow being involved in the prosecution of the application?
MR. BONELLA: Objection. Asked and answered.
A. No, I do not recall -- I had no direct interactions with Mr. Woodrow, so if he did or didn't, I wouldn't -- I wouldn't be privy to it.
Q. Okay. Do you know who actually drafted the patent application?
THE WITNESS: Is that --
MR. BONELLA: If you know, you can answer yes or no.
A. I would say it was a joint drafting between myself and, my recollection was, Mr.

Page 265

Goodwin.
Q. What do you mean by a "joint drafting"?
A. That there would -- there would be -- that Mr. Goodwin took my input, drafted the basic patent, and then would ask me for my input, and it was an iterative process.
Q. Okay. Just to be a bit more specific about that, if I understand your testimony correct, you provided information to Mr. Goodwin, correct?
A. (Nods.) Yes.
Q. You have to verbalize.
A. Yes. Thank you.
Q. And then he took that information and prepared a draft of the application?
A. Correct.
Q. Is that the way it went?
A. Correct.
Q. And then you reviewed the draft?
A. Correct.
Q. And gave comments?
A. Correct.
Q. Or -- okay. And then did you see a second draft?
A. I would -- I definitely recall a second draft.

Page 266

Q. And did you give further comments?
A. At that point I can't remember how many iterations, but it was more than one.
Q. Okay. Well, when you -- the "more than one" means at least two?
A. Yeah.
Q. And you recall giving comments on the first draft that you saw, is that correct?
A. Yes.
Q. And do you recall giving comments on any further -- further iterations?
A. I don't recall. I don't recall how many iterations that one went.
Q. I know, but you know there were at least two. And what I'm trying to get is whether you recall giving comments after the first draft.
A. I don't recall.
Q. Okay. Were any of the other named inventors involved in the process of providing information for purposes of the preparation of the application? That you know of.
MR. BONELLA: Object to form.
A. Yeah. They wouldn't have gone directly through me. They would have been through -- directly to the attorney, so I don't have any

Page 267

recollection that -- of their input.
Q. Okay.
A. But I may not have had admissibility --
Q. Let me just ask a couple of follow-ups to that.
A. Please.
Q. In any of the meetings that you had with the attorneys, were any of the other inventors present?
MR. BONELLA: Object to form.
Q. And any other named inventors present?
MR. BONELLA: Object to form.
A. I do have a recollection of a meeting with Al.
Q. Al Hunter?
A. Yes.
Q. With the patent attorneys?
A. I do have that recollection. It's been some time ago, but I do have that recollection.
Q. So, at least -- and was that meeting that you recall that Mr. Hunter was present at, was that one of the meetings for the purpose of giving information to the patent attorneys for the preparation of this application that led to the 446 patent?

Page 268

A. Yes. And by "meeting," in this case I'm referring to either face-to-face or e-mail correspondence.
Q. Okay. Well, let me follow up on that. With the one with Mr. Hunter, do you just -- did you send -- when you meant e-mail, are you talking about a joint e-mail that --
A. An e-mail stream that people are commenting on.
Q. Right. Was e-mail being used in the '90, '91, '92 time frame?
A. Yeah. We had e-mail in '91, '92.
Q. And that's what you recall? This is some e-mail streams that Mr. Hunter was involved in that led to the preparation of the application that led to the 446 patent?
A. Yeah, I -- I do recall a -- at least one conversation where --
MR. BONELLA: Caution you not -- if it's with an attorney --
THE WITNESS: Yes.
MR. BONELLA: -- don't disclose the substance of the conversation. Describe the circumstances.
A. Yeah, I remember one conversation -- I do

Page 269

remember one conversation that involved the attorney and Mr. Hunter and myself.
Q. Was that -- your conversation, was that in person, over the phone, or what?
A. Actually, I do remember one in-person conversation at an early stage of patent drafting.
Q. Between you, Mr. Hunter, and the attorneys?
A. Yes.
Q. And do you recall which attorneys?
A. My recollection would be Mr. Goodwin.
Q. Other than that communication, is there any other involvement of Mr. Hunter that you can recall?
A. I do not recall any other involvement.
Q. How about Mr. Taylor, do you recall any involvement of Mr. Taylor in connection with the preparation of the application that led to the 446 patent?
A. I don't recall any involvement of Mr. Taylor.
Q. How about Mr. Jamiolkowski? Was there -- are you aware of any involvement that Mr. Jamiolkowski had in connection with the preparation of the application that led to the 446 patent?

Page 270

A. I do remember conversations with Mr. Jamiolkowski. I do not recall whether Mr. Goodwin was part of those conversations, but I do recall conversations with Mr. Jamiolkowski regarding the 446 patent.

Q. Okay. Let me ask you about any conversations you had with Mr. Jamiolkowski outside the presence of attorneys. Do you recall whether there were any such conversations?

A. There was conversations.

Q. Tell me, when did those occur?

A. Throughout the -- throughout the entire patent drafting process.

Q. What do you recall about any of those conversations?

MR. BONELLA: This is a little tricky. If you're -- if you are -- or Dennis was relaying legal advice that was received from an attorney, that's still attorney/client privileged information. If you're discussing things that did not involve the attorney or were not asked by your attorney to do or to find out, you're discussing technical aspects of the invention, that would probably not be privileged. So, this is a little tricky, but you be careful that you're not

Page 271

disclosing any legal advice that was received by either you or Dennis regarding the drafting of the patent application or that had to do with the patent application.

A. Okay. Well, the scope of the conversations that I recall revolve around bioabsorbable constructions of heterogeneous sutures, in particular various copolymer types that would be advantageously blended.

Q. Did you -- do you recall any conversations with Mr. Jamiolkowski about non-absorbable materials to go into the suture?

A. I don't have any recollections of -- Dennis -- Dennis's forte was absorbable polymers.

Q. So, you don't recall any conversations --

A. I don't recall any.

Q. -- with him with respect to non-absorbable materials?

A. No.

Q. Do you -- going back to the drafts, do you know whether any of the other inventors reviewed drafts of the application?

A. I don't know.

MR. BONELLA: Object to form.

Q. Do you recall when you reviewed the first

Page 272

draft of the application?

A. Specific month --

Q. Well --

A. -- or do I recall --

Q. In any way you can answer the question. I mean, I'm obviously not asking for the specific date.

A. Yeah.

Q. But any approximations that you can give me.

A. Actually, I don't have the recollection of the first review.

Q. Okay. Do you recall about how much -- how long before the filing -- the February 19, 1992 filing date -- that that review was?

MR. BONELLA: Objection. Calls for speculation.

A. February 19th filing?

MR. BONELLA: Asked and answered.

A. No, I just don't. It's --

Q. You don't know?

A. I -- specific months, years, no.

Q. I mean, can you give me --

A. No.

Q. -- approximation? Was it days before,

Page 273

weeks before, months before?

A. It certainly wasn't days before.

Q. Okay. Anything more than that?

A. The process was always longer than, you know, it seemed like it should be. No, I'm sorry. I just don't recollect.

Q. Okay. Do you recall the approximate amount of time it took from when you first met with the attorneys until you received a draft application?

MR. BONELLA: Objection. Asked and answered.

A. No.

Q. Excuse me?

A. No.

Q. Do you recall the amount of time between when you received the first draft and you gave comments to the attorneys?

A. No.

Q. Do you recall the amount of time from the time you gave comments to the attorneys on the first draft to when you received a second draft?

A. No.

Q. I know -- I know you said you recall at least a second draft, correct?

Page 274

A. Yes. Yes.
Q. All right. Do you recall the period of time from receiving the second draft to any other comments that you gave?
A. No.
Q. Do you recall the amount of time from your receipt of the second draft to the filing of the application?
A. It's just not -- the date -- the timing's just not clear to me. It's just too many patents, too long ago.
Q. So, is your answer you don't know?
A. My answer is, I don't know.
Q. All right. I apologize if I asked this: Do you recall whether you made comments a second time?
A. I don't recall.
Q. Whether you did or you didn't?
A. No.
Q. Going back to the -- the first draft that you received, do you recall the changes that you suggested?
A. That I suggested?
Q. Yes, sir.
MR. BONELLA: That's a yes-or-no answer.

Page 275

A. No.
Q. You don't know. Did you -- did you make -- did you suggest changes?
A. I have a recollection that there were some edits that I had suggested.
Q. Uh-huh.
A. But certainly not any specifics.
Q. What -- you can't tell me any of the specifics that you suggested?
A. Definitely not.
Q. Looking at Defendant's Exhibit 10, the patent, and looking at the specification of the patent -- do you have the patent in front of you, sir?
A. Yes.
Q. What?
A. I believe so. Is that -- (Witness reviews document.) Yes.
Q. Starting from Column 1 and until -- until the claims in Column 8, do you recall any -- do you recall any differences -- well, strike that. Were there -- there were -- I take it there were differences from the first draft to what you see in the specification of the 446 patent, Column 1 through Column 8 before the claims, is that

Page 276

correct?
A. (Witness reviews document.) I -- I don't know.
Q. This may be identical to what you saw -- the first draft?
A. It would be unlikely, but it may be.
Q. It's possible?
A. It's possible, but unlikely.
Q. But unlikely.
A. Yeah.
Q. Do you recall any of the changes?
A. I don't.
Q. If there were changes -- in the likely event that there were changes, do you recall any of the changes from the first draft to what appears in the specification of the 446 patent?
MR. BONELLA: That's a yes or no whether you recall or not. Otherwise, it's probably privileged. So, just get a yes or no first.
A. Yes.
Q. You do recall changes. What changes do you recall?
MR. BONELLA: Okay. That's privileged. If that's information that was communicated to your attorney in response to a request for drafting the

Page 277

application, that's privileged, so I'm instructing you not to answer.
MR. SABER: Mr. Bonella, I didn't ask --
MR. BONELLA: You asked for changes.
MR. SABER: No, I didn't ask what changes he gave. I didn't ask. I just asked what changes from the first thing he saw -- from the first draft to the specification. I just asked what changes.
MR. BONELLA: Your answer necessarily -- the answer to that question necessarily conveys what changes were -- were made. So, it necessarily conveys what was talked about between the attorney and the inventor, so --
MR. SABER: I don't agree with that, but that's why I wanted to make that clarification to see if you'll let him answer the question.
MR. BONELLA: I think -- I don't understand the difference, because it necessarily asked him what changes he recalls from the first draft to this.
MR. SABER: To what's in the spec, right.
MR. BONELLA: Right. So, that necessarily -- necessarily tells -- the answer to that question necessarily tells whether the -- what the changes were, either by the attorney or by the inventor

Page 278

going back and forth. And that's privileged information. I instruct him not to answer.
MR. SABER: I disagree with you, but --
Q. Will you answer the question?
MR. BONELLA: I instruct you not to answer the question.
A. I'll accept my -- I'll accept Mr. Bonella's recommendation.
Q. Okay. Looking at the specification of the 446 patent, do you recall in what areas of the -- in what areas of the specification there were changes compared to the first draft that you saw which asked --
A. You're asking --
MR. BONELLA: The whole patent, and you can answer that yes, whether you recall. That's yes or no.
Q. Let me try to ask it --
MR. BONELLA: It's a yes or no.
Q. -- in component parts. You see, first it says on Column 1, "Background of the Invention." Do you recall whether there were any changes from the first draft to the -- what we see in the specification to the background of the invention?
MR. BONELLA: That's yes or no you recall.

Page 279

A. No.
Q. No, you don't recall?
A. I don't recall if there were any changes to that.
Q. How about to the summary of the invention, do you recall whether there were any changes from the first draft to what's in the specification?
MR. BONELLA: Again, yes or no.
MR. SABER: Or I don't recall.
MR. BONELLA: Or I don't recall. Right. Thank you.
MR. SABER: Or I don't know.
MR. BONELLA: Right.
A. No, I don't recall.
Q. You don't know if there were changes to that section.
A. (Witness nods.)
Q. How about the brief description of the drawings, do you know if there were any changes in that section?
A. Do not recall.
Q. How about in the detailed description of the invention, do you know whether there were any changes in that section? And again, this is from the first draft to what appears in Defendant's

Page 280

Exhibit 10.
A. I do recall.
MR. BONELLA: Yes or no.
A. Yes.
Q. You do recall there were changes in the section of the detailed description of the invention.
MR. BONELLA: Yes or no.
A. Yes.
Q. Okay. What changes do you recall?
MR. BONELLA: And I'll instruct you not to answer. It's attorney/client privilege.
Q. Will you answer the question?
A. No.
Q. Let me ask about the examples. It starts on Page 6. Do you recall -- and that would go -- examples goes from there until the claims.
A. (Witness nods.)
Q. Do you recall whether there were any changes in that section from the first draft to what appears in Defendant's Exhibit 10?
MR. BONELLA: Again, it's yes, no, I don't know, I don't recall.
A. Yes, I do remember there were changes.
Q. Okay. What changes do you recall?

Page 281

MR. BONELLA: I instruct you not to answer. That's attorney/client privilege.
A. I accept the recommendation.
Q. Will you answer the question?
A. No.
MR. SABER: Could you mark this.
(DMI095016 marked Exhibit 79.)
(DMI095017 marked Exhibit 80.)
Q. Doctor Steckel, let me show you what's been marked as Defendant's Exhibits 79 and 80 and ask you if you've seen these exhibits before or seen these documents before?
A. 79 and 80?
Q. Yes, sir.
A. (Witness reviews document.) Yes. I do remember these.
Q. Okay. Looking at Exhibit 79, this is dated February 3, 1992, is that correct?
A. Right. Right.
Q. In the second paragraph it says that, "Mark received comments from the remaining coinventors. I understand that Mark received comments from the remaining coinventors." Do you see that?
A. I do see that.

Page 282

Q. Is that understanding that you're the Mark that's being referred to there?
A. Yes.
Q. Did you, in fact, receive comments from the remaining coinventors?
A. It would have been practice for me to distribute the draft to all the inventors for comments. They may or may not have made any.
Q. But is it your recollection that you -- you got the drafts and you were the one responsible for distributing the draft to the coinventors?
A. That's actually not my recollection, but it would have been my practice to circulate it to all the inventors.
Q. Well, what is your -- what is your recollection in this instance with respect to this application?
A. I have no recollection.
Q. Do you recall whether you received comments from the remaining coinventors?
A. No, I do not.
Q. Okay. Do you see in the next paragraph it refers to two voice mail messages for Mark during the first week of January?
A. Yes.

Page 283

Q. This is from Mr. Goodwin, this memo, correct?
A. Yes. Yes.
Q. Do you recall receiving voice messages from Mr. Goodwin during the first week of January 1992?
A. No, I do not.
Q. Do you have any reason to doubt the accuracy of what's stated here?
A. No, I do not.
Q. Did you -- do you recall responding to Mr. Goodwin between the first week in January and February 3 of 1992? Strike that. Do you recall communicating with Mr. Goodwin between the first week in January and February 3 of 1992?
A. No, I do not recall.
Q. Do you have any reason to doubt that you did not communicate with him during that time period?
A. Between the 1st week of January and February 3rd? No, I have no reason to doubt Mr. Goodwin's statements here.
Q. Okay. Now, in the -- in the second paragraph it says, "I sent a substantially-completed draft, including examples

Page 284

and drawings, to Mark Steckel for review and comment." Do you see that?
A. Yes.
Q. Do you recall when you received -- do you recall that you received a draft that's being referred to in this exhibit? Strike that. Do you recall receiving the draft that's being referred to in this exhibit?
A. After reading this document, I do recall.
Q. Okay. Do you know how long you had the draft?
A. No.
Q. From reading this document, is it a fair statement that you had it -- do you know whether you had it by the first week in January?
A. I would say I had it by the first week of January.
Q. And when did you respond to Mr. Goodwin with -- in connection with that draft that you had?
A. I don't know.
Q. All right. It wasn't before February 3, 2002, was it?
A. It would -- I would -- it would appear not from this, but I don't know.
MR. BONELLA: Make sure you get the

Page 285

question right. The question was, was it before February 3rd, 2002? That's the question.
THE WITNESS: Oh, 2002.
MR. SABER: Oh. I'm sorry. 1992. Thank you, Mr. Bonella.
A. I have a recollection of this being in process when Matt wrote this, but I -- I don't know if it was before or after.
Q. All right. Okay. Let's look at Defendant's Exhibit 80, if we could.
A. 80, yes.
Q. Do you recall that one?
A. Yes.
Q. That's from Barbara Schwartz. She was your supervisor?
A. Yes.
Q. To you?
A. Yes.
Q. And is that sending along the attached memo? Do you have an understanding that the attached memo is referring to Defendant's Exhibit 79?
A. Yes.
Q. And this memo asks you to respond to Matt Goodwin's request?

Page 286

A. Yes.
Q. Do you have any recollection whether you had already responded to Matt Goodwin's request prior to receiving this February 10, 1992 memo?
A. I have a recollection of responding right after this February 3rd --
Q. This February 3rd or the February 10th?
A. The February 3rd.
Q. Well, when did you receive the February 3rd memo?
A. I don't know.
Q. You're not an addressee on the February 3rd memo, right?
A. No, but I remember hearing about it.
Q. Well, the February 10 memo attaches the February 3rd memo, correct?
A. Yeah, but I remember hearing about it even before.
Q. Okay. Do you know whether you responded --
A. Could I state that I had already moved from New Jersey to Ohio at this point?
Q. Okay. Sure.
A. So, I was -- I remember -- I remember this memo, and I remember --

Page 287

Q. "This memo" being which one?
A. Matt Goodwin's memo.
Q. Right.
A. And I remember someone calling me and saying, Matt wrote a memo to your old boss, Barbara Schwartz, that expressed some frustration.
Q. Right. And the frustration being that he hadn't heard back from you.
A. Right. During my move, 'cause I was moving literally in January of '92.
Q. All right. Do you recall whether you responded to -- was it -- hearing about the February 3 memo -- the February 3, 1992 memo that caused you to respond to Mr. Goodwin?
A. Yes.
Q. And you're not sure whether you actually heard about the memo before you got -- before you actually got it in connection with Defendant's Exhibit 80 on February -- on a document dated February 10?
MR. BONELLA: Object to form. Misstates the record.
A. I have -- I have a recollection of hearing about this memo before -- before the follow-up memo.

Page 288

Q. And just so you're -- so the testimony is clear, do you recall when you responded to Mr. Goodwin -- to Mr. Goodwin's February 3 memo?
A. No. I'm sorry. I do not remember the date I responded.
Q. And you don't recall whether it was before or after receiving the February 10 memo?
A. No, I do not.
Q. Let's turn to Defendant's Exhibit 10, the 446 patent if we could, sir. And if you could turn to Column 1, which is on -- well, Column 1. And the first paragraph under "Background" says, "This invention relates to braided multifilaments and especially to sterilized braided multifilaments suitably adapted to use as surgical sutures or ligatures." Do you see that?
A. Yes.
Q. What did you mean by that paragraph?
A. I don't know how else to say it.
Q. Why were --
A. Applies to surgical sutures.
Q. Excuse me?
A. It applies to sterile surgical sutures or ligatures.
Q. What's the difference between a surgical suture and a ligature?

Page 289

MR. BONELLA: Object to form. Calls for expert testimony.
A. My understanding there's not a major difference. It's more how they're used than the actual product.
Q. Why were you including both surgical sutures and ligatures in this paragraph?
MR. BONELLA: Object to form. Assumes facts not in evidence.
A. Ethicon's business was in sutures and ligatures.
Q. Do you think that this is an accurate statement of what the invention -- your invention relates to?
MR. BONELLA: Object to form.
Q. This paragraph.
MR. BONELLA: Object to form.
A. Yes.
Q. Could the braid that the -- the braided multifilaments that are the subject of this patent application -- this patent, could they be adapted for use as either sutures or ligatures?
A. Yes.
Q. And why is that?

Page 306

Q. Is that referring to obtaining braid properties for any reason other than the mechanical interlocking or weaving of the individual yarns?
A. (Witness reviews document.) Correct. There has to be some mechanical interlocking.
Q. Is there anything else that's referred to in that sentence, other than the mechanical --
A. No. No, not that I --
Q. -- mechanical interlocking or weaving of the individual yarns?
A. Not that I can interpret from this.
MR. SABER: Okay. Why don't we take a break.
(Recess was taken.)
Q. Doctor Steckel, could you turn to Column 6 of the patent. I want to ask you about the paragraph that begins on Line 5 that goes through Line -- about 17. Specifically, I want to ask you about the question about two-thirds -- the sentence about two-thirds of the way down: "However if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated, saving expense as well as avoiding the associated braid stiffening." If you need to read

Page 307

the whole paragraph to answer my question, go ahead. My question is, what's your understanding of that sentence?
A. (Witness reviews document.) Okay. What's my understanding of the last sentence of that paragraph?
Q. Yes, sir.
A. (Witness reviews document.) That this was one potential feature of the heterogeneous braid was that it may or may not need a coating.
Q. If you -- what does it mean that if you -- why could conventional coating be eliminated if a significant "-- if the braid is engineered to possess a significant fraction of the lubricious yarn system"?
A. Why is that the case?
Q. Yes, sir.
A. My understanding is one of the reasons braids are coated is to add lubricity for the knot tie-down, which may be achieved in the right heterogeneous braid system.
Q. I'm just trying to understand your -- your testimony. When you say the right type of heterogeneous system, what are you referring to?
A. As we state, one in which there is a

Page 308

significant fraction of the lubricious yarn.
Q. In that circumstance, is this explaining that you'd get the same benefits as you'd get from coating?
MR. BONELLA: Object to form.
A. Would you get the same benefits? I would say you would get some of the same benefits.
Q. Enough of the same benefits that you don't need to have a coating?
A. I don't know if you wouldn't need any coating.
Q. I'm sorry?
A. I don't know if -- I don't know if -- if you wouldn't need any coating.
Q. What does it mean when it says that the conventional coating may be eliminated?
A. Okay. It may be eliminated, so certain embodiments of the heterogeneous braid may give the same performance as a nonheterogeneous braid with a coating.
Q. Okay.
A. In those embodiments, you may be able to get by with no coating.
Q. Now, up further in the paragraph -- up earlier in the paragraph where it says, "If

Page 309

desired, the surface of the heterogeneous multifilament braid can be coated --"
A. Yes.
Q. Excuse me "-- to further improve handle ability, knot tie-down performance of the braid."
A. Yes.
Q. When you use the words -- what's your understanding of the words "if desired"? Is it your understanding that means that you can or cannot add coating? You may or may not add coating?
A. You may or may not. That's my understanding.
Q. Coating is -- is optional. Is that -- well, strike that. Is it -- is it your understanding that this sentence means that if you do add coating, it would further improve the handle ability and knot tie-down performance of the braid?
MR. BONELLA: Object to form.
A. The coating's -- the reason why people coat sutures is to improve handle ability and knot tie-down.
Q. Do you know why the word "further" is used in that sentence?
A. I think it is stating that you could get

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	**Civil No. 04-12457 PBS**

Declaration of Dr. Matthew Hermes

I submit this declaration in support of DePuy Mitek's Memorandum in Opposition to Arthrex's Motion for Summary Judgment.[1]

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture

[1] I noticed a few citation errors in my previous declaration submitted in support of DePuy Mitek's Claim Interpretation of the Hunter Patent. The citations in ¶8 should be (Tab C) and (Tab C and D), respectively. The citations in ¶¶9 and 12 should be (Tab B). The first citation in ¶11 should be (Tab B).

products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post treatment, stretching, annealing, coating, packaging design, sterilization, testing, assisting with obtaining 510(k) approval, and quality control.

2. In 1996, I authored the book "Enough for One Lifetime," the biography of Wallace Carothers, the inventor of Nylon. While writing this book from 1989-1996, I researched and studied the origins of synthetic fiber science including the history and development of nylon and polyester.

3. Before I worked at U.S. Surgical Corporation, I was a Research Director at Virginia Chemicals, at Celanese Co. from 1979-1983. Prior to being a Research Director, I was a Research Chemist, Supervisor, at E. I. DuPont from 1959-1979. At DuPont, I work with triaxial support systems and supervised a group that worked on elastomer coated fabrics.

4. From 1992-1994, I was an Adjunct Professor of Chemistry at the University of Wyoming. From 1995-1997, I was a Consultant at Colorado Advanced Technology Institute. In 2001 and 2006, I received two Small Business grants from the NIH for the development of unique all plastic manual wheelchairs and worked with Turbo Wheelchair company to develop, manufacture, and sell these unique devices.

B. Education

5. I have a Bachelor of Science in Chemistry from St. John's University, Brooklyn, NY, 1955. I have a Ph.D. in Chemistry from the University of Maryland, 1959. My mentor was Professor William Bailey who developed one of the earliest polymer science research groups in the country. My doctoral thesis related to polymers made using the Diels-Alder reaction. I also have a Masters of Arts in Liberal Studies from Wesleyan University, 1992.

6. A copy of my CV is attached under Ex. 1. A list of my publications and patents are set forth in my CV.

7. It is my understanding that a patent claim is invalid if it is not novel (which I understand is referred to as being "anticipated"), if a single prior art reference teaches, expressly or inherently (necessarily present), all of the claim limitations arranged in the same manner as the claim and enables one of ordinary skill in the art to make and use the invention. I understand that the test for lack of novelty is generally a two-part test. First, the meaning and scope of the claims are determined by the Court. Second, once the claim scope has been determined or construed, the next step in assessing a patent claim's validity is deciding whether one piece of prior art describes all of the claim limitations arranged as claimed. Because the Court has not yet construed the claims of U.S. Patent No. 5,134,446, I have been asked to assume a certain claim construction.

8. It is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not anticipated by U.S. Patent No. 5,318,575[2] ("Chesterfield") because the 575 patent does not teach, either expressly or inherently, all the claimed limitations of these claims.

II. Claims 1, 2, 8, 9, and 12 of The 446 Patent Are Not Anticipated By Chesterfield

A. Legal Framework For My Opinion of No Anticipation

9. The patent laws form the legal framework for my opinions. My understanding of the U.S. Patent Laws is as follows. I understand that the patent statute states that patents are presumed valid. 35 U.S.C. §282. I further understand that each patent claim is presumed valid, and therefore an invalidity analysis must be done on a claim-by-claim basis. I understand that

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[2] I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that Chesterfield may not be prior art. For purposes of this report, I have been asked to assume that Chesterfield qualifies as prior art.

because of this presumption, Arthrex or Pearsalls must put forth “clear and convincing” evidence of invalidity to overcome this presumption of validity. It is my understanding that this a higher burden of proof than a preponderance of the evidence standard, but less than a reasonable doubt standard.

10. It is my understanding that a patent claim is invalid if it is not novel (which I understand is referred to as being “anticipated”), if a single prior art reference teaches, expressly or inherently (necessarily present), all of the claim limitations arranged in the same manner as the claim and enables one of ordinary skill in the art to make and use the invention. I understand that the test for lack of novelty is generally a two-part test. First, the meaning and scope of the claims are determined by the Court. Second, once the claim scope has been determined or construed, the next step in assessing a patent claim’s validity is deciding whether one piece of prior art describes all of the claim limitations arranged as claimed. Because the Court has not yet construed the claims of U.S. Patent No. 5,134,446, I have been asked to assume a certain claim construction.

11. It is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not anticipated by U.S. Patent No. 5,318,575[3] (“Chesterfield or 575 patent”) because the 575 patent does not teach, either expressly or inherently, all the claimed limitations of these claims.

12. Arthrex asserts that Chesterfield “discloses every limitation of the asserted claims.” I disagree. The 575 patent does not disclose many limitations of claims 1, 2, 8, 9, and 12 of the 446 Patent.

[3] I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that Chesterfield may not be prior art. For purposes of this report, I have been asked to assume that Chesterfield qualifies as prior art.

13. The 575 patent does not disclose to one of ordinary skill in the art a heterogeneous braid of the claimed yarns from the first-fiber forming materials with the second fiber-forming materials in direct intertwining contact. Further, the 575 patent does not teach a suture having a braid of PE (including UHMW PE) with PET, Nylon, or aramid. I understand that in order for the 575 patent to anticipate the 446 patent claims, it must disclose every limitation of the 446 Patent claims (expressly or inherently) arranged in the same way as claimed in the 446 Patent claims. Because the 575 patent does not teach all of the limitations of the claimed invention arranged in the same way, it is my opinion that there is no anticipation.

14. In general, Arthrex picks and chooses different teachings of the 575 patent and combines them in a way that is not described in the 575 patent and then concludes that the 575 patent teaches the claimed invention. Basically, Arthrex forms the claimed invention by selecting teachings about a sternum closure device in the 575 patent and combining them with select teachings about a suture repair device in the 575 patent. But I disagree with Arthrex's analysis because the 575 patent does not expressly or inherently describe the claimed invention. I address some of Arthrex's specific points below.

15. Arthrex cites to column 3, lines 61-67, of Chesterfield as disclosing nylon or PET. I disagree. This citation does not refer to nylon or PET. In fact, column 3, lines 61-67, specifies that the material 20 is a "bioabsorbable polymeric material such as . . . polyester" (Ex. 2 at 3:63-67). Neither nylon nor PET are bioabsorable polyesters; they are non-absorbable materials. Thus, column 3, lines 61-67 is not a disclosure of either PET or nylon. Column2, line 62 of the 575 patent describes a sternum closure device, not a suture.

16. Arthrex also cites to column, 3, lines 61-67, of Chesterfield as disclosing nylon or PET braided with UHMW PE in a suture. But I disagree. The 575 patent at column, 3, lines 61-67,

describes that fibers 20 are used in the outer structure in the sternum closure ribbon 10, not a suture. Thus, this citation to col. 3, lines 61-67 does not teach nylon or PET braided in a suture, much less braided in direct intertwining contact with UHMW PE.

17. Arthrex cites the filler yarns 20 of the sternum closure device as being braided with the UHMW PE in the spiroid braid of Fig. 7. But the filler yarns 20 are from a sternum closure device (Figs. 2 and 4) and the UHMW PE (to which he cites) is from a spiroid braid (Fig. 7). Thus, they are not braided in direct intertwining contact as required by the 446 patent claims.

18. Further, Chesterfield does not teach a heterogeneous braid for the braided fibers 20 in the sternum closure device 10 (below). Rather, Chesterfield teaches that the braided fibers 20 are in a homogeneous woven structure (Ex. 2 at 3:61-4:1, 4:39-47). Therefore, his citation to Chesterfield's sternum closure device does not disclose nylon, aramid, or PET braided in direct intertwining contact with PE in a suture, as claimed in the 446 Patent.

19. Again, Arthrex piecemeals two materials from two different structures to describe the heterogeneous braided suture as claimed in the 446 Patent. Specifically, Arthrex takes the UHMW PE from the core of the hollow braid of Figs. 8 and 9 and matches it with either the (1) bioabsorbable polyester of the sternum closure device or (2) the material of the spiroid braid of Fig. 7. This picking and choosing of two different materials from two different structures does not teach a single suture construction having the claimed first and second fiber forming materials braided in direct intertwining contact as claimed in the 446 Patent.

20. Arthrex also cites to column 7, lines 43, 59-60, as disclosing a heterogeneous braid with direct intertwining contact where one of the yarns is PE. But column 7, lines 59-60 of Chesterfield only describes PE in the core. The PE referred to in column 7, lines 59-60, is not in the sheath, is not described as braided with another material, is not described as braided with the

claimed second fiber-forming materials (nylon, aramid, or PET), and is not described as braided in direct intertwining contact with the claimed second fiber-forming materials. Also, column 7, lines 26 and 38 of the 575 patent describe a product with 100% Spectra sheath.

21. Arthrex also cites to claims 11 and 12 of the 575 patent as disclosing nylon and polyester respectively braided in direct intertwining contact with UHMW PE in a heterogeneous suture braid as claimed in the 446 patent. I disagree. Claims 11 and 12 of the 575 patent refer to second non-absorbable fibers as being formed from either nylon or polyester. But claims 11 and 12 of Chesterfield do not specify how the second fibers are braided with the claimed first fibers. For example, Chesterfield claims 11 and 12 do not recite that the first and second fibers are braided in direct intertwining contact, as opposed to a core-sheath arrangement (like that described in Chesterfield Figs. 8, reproduced below, and 9), with the first fiber materials only in the core and the second fiber materials only in the sheath.

22. Further, claims 11 and 12 recite a "method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue..." (Ex. 2 at 8:29-38; 60-64). It is my opinion that this refers to a method of using the sternum closure device, not a suture, because a sternum closure goes "about" the margins of tissue (Ex. 2 at Fig. 1) while a suture goes through tissue. Thus, claims 11 and 12 do not refer to a suture and therefore cannot teach all the limitations of the claims of the 446 Patent.

23. Chesterfield at column 4, lines 9-23 does not disclose the second fiber forming materials (PET, nylon, or aramid) braided in direct intertwining contact with the first-fiber forming materials. That portion of Chesterfield does not explicitly mention nylon, aramid, or PET. Although, that citation does state that "[a]ny number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated"

(Ex. 2 at 4:20-24), it does not disclose how these materials are selected or arranged, such that a person of ordinary skill in the art would understand that nylon, aramid, or PET are necessarily disclosed and arranged as claimed in the 446 patent. For example, it does not disclose PET, Nylon, or aramid braided in direct intertwining contact with UHMW PE, as claimed in the 446 Patent.

24. I understand that for any claimed limitation to be inherently disclosed, it must necessarily be disclosed. I see no reason why PET, nylon, or aramid is necessarily disclosed as being braided with UHMW PE in direct intertwining contact in a suture as claimed in the 446 Patent based on Arthrex's citation to column 4 of the 575 patent. For example, Arthrex provides no explanation as to why one of ordinary skill in the art finds that this statement discloses selecting either PET, nylon, or aramid from the universe of possible yarns. Nor does he provide an explanation of why only one yarn would be picked to be braided with PE in direct intertwining contact when the 575 patent refers to "any combination" of the universe of yarns and does not specify any particular braiding arrangement.

25. I note that when Arthrex was prosecuting an application, which ultimately issued as the 234 patent, Arthrex represented to the Patent & Trademark Office that Chesterfield "does not disclose an example of a braided sheath that includes a blend of both UHMWPE and polyester" (Ex. 3 at DMI041091).

26. Thus, Arthrex's patent counsel agreed with me when it was prosecuting its own patent application.

27. Also, claim 9 of the 446 patent is not anticipated by Chesterfield for the additional reason that Chesterfield does not describe the limitation of claim 9 that the "volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent."

28. Arthrex argues that Chesterfield "discloses all of the subject matter of claim 9." I disagree. It is my opinion that Chesterfield does not disclose all of the limitations of claim 9, arranged as claimed. As described in my previous report with reference to claim 1 of the 446 patent, Chesterfield does not disclose many of the limitations of claim 1, which are also limitations of claim 9.

29. I also disagree with Arthrex's assertion that Chesterfield discloses the limitation that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (Ex. 4 at 10:9-11) in column 4, lines 8-24, and Figure 6 of the 575 patent. Figure 6 of the 575 patent is entirely silent regarding the volumetric ratio of any sheath and core materials. I also note that Figure 6 is a spiroid braid that does not disclose a core. Also, column 4, lines 8-24, of the 575 patent does not discuss any volume fractions of materials, much less a volume fraction of PE in the sheath and core relative to the remainder of the suture. Thus, because Chesterfield does not disclose a suture having all of the limitations of claim 9, arranged as claimed, it is my opinion that Chesterfield does not anticipate claim 9 of the 446 patent.

30. As I have opined previously with respect to U.S. Patent No. 4,610,688, fibers which are just straight fibers around which other fibers are braided and not in direct intertwining contact. The 688 patent teaches a ligament prosthesis, not a suture (Ex. 5 at 2:14). Element 9 in the 688 patent is a straight fiber, while the elements 11 and 13 are helically wound around element 9 (Ex. 5 at Fig. 1 and 2; 3:65-4:14). Thus, element 9 is not mechanically interlocked with either element 11 or 13 and is not braided with either element 11 nor 13 “in direct intertwining contact,” as claimed in the 446 Patent. For example, in a direct intertwining braided construction, one set of yarns is interlocked with the other, so that they are held within the braid

by the other set of yarns (*see* Ex. 4 at 5:18-26). In contrast, in the 688 patent, fibers 9 are not interlocked with fibers 11 or 13.

III. The Inventors Reduced the Claimed Invention to Practice

31. Generally, I understand that in order for a claimed invention to be actually reduced to practice, the invention must have been made and evaluated so that the inventors knew that it would work for its intended purpose.

32. I have reviewed Dr. Steckel's deposition transcript, Dr. Jamiolkowski's testimony, and Dr. Steckel's lab notebooks. It is my opinion that the inventors had made and tested a braided suture that was suitable for its intended purpose and had proved the concept of the invention at least as early as February 1989 and December 1989. I understand from Dr. Steckel's testimony that he referred to some of the work that led to the 446 patent as "Composite Braid Evaluation" or "CBE" (Ex. 6 at 135:1-21).

33. Dr. Steckel's notebook describes conception of the claimed invention at least as early as June 6, 1988 (Ex. 7 at DMI002617). Dr. Steckel describes his idea as "[a] preliminary evaluation of composite braids, i.e., braided sutures constructed of two or more fiber types designed to realize the beneficial properties of each polymer" (*id.*). He further states that the composite sutures to be evaluated included carrier blended "PET/PTFE" and "PET/PP" yarns in which blending occurs when two different yarns reside on different carriers during the braiding operation. (*Id.*). Thus, at least as early as June 6, 1988, he had described the broad concept of a heterogeneous braided suture with two yarns in direct intertwining contact and provided two specific examples of braiding PET/PTFE and PET/PP (*see also* Ex. 8 at 99:7-25; 100:20-23; 102:10-17; 127:12-21; Ex. 6 at 159:6-23; 160:17-22; 161:4- 10).

34. Dr. Steckel's notebook and testimony confirm that he built a suture braid as claimed in the 446 patent at least as early as June 6, 1988 (Ex. 7 at DMI002618; Ex. 8 at 127:12-128:21; Ex.

6 at 218:21-25). For example, Dr. Steckel built the CBE-15 prototype on June 6, 1988 with a carrier braider ("CB") (Ex. 7 at DMI002618). The CBE-15 braid was made from braid of 51% PET and 49% PTFE by volume (*id*.). The yarns used to construct the CBE-15 braid are specified on page DMI002619 of Dr. Steckel's notebook (*id*. at DMI002619). In June 1988, Dr. Steckel performed basic suture testing on CBE-15 including straight tensile and knot tensile testing (Ex. 6 at 219-220). Thus, at least as early as June 6, 1988, Dr. Steckel had conceived of the idea of braiding two materials, of the type claimed in the 446 patent, in direct intertwining contact to form a suture and had made a suture having these characteristics.

35. Dr. Steckel's notebook describes prototypes that he had constructed and tested as least as early as February 2, 1989 (Ex. 7 at DMI002635-38: Ex. 6 at 220:1-221:2). He had constructed PET/PTFE carrier braided sutures designated as CBE-15 having PET and PTFE yarns which were carrier braided in direct intertwining contact (Ex. 7 at DMI002635-36; Ex. 6 at 222:7-223:20). Dr. Steckel testified that "full characterization" of the braids had been completed at least as early as February 1989 (Ex. 6 at 218:12-219:6). His notebook describes various testing that he performed on the braided sutures (Ex. 7 at DMI002637; Ex. 6 at 222:2-11).

36. Dr. Steckel had constructed and evaluated a suture that is within the scope of claims 1, 8, and 9 of the 446 patent at least as early as February 1989 (except it was not sterile). He had built a "heterogeneous suture" of PTFE and PET yarns. The PTFE and PET yarns were "continuous and discrete yarns" as claimed in the 446 patent (Ex. 4 at 8:65). They were also in "direct intertwining contact" because they were carrier braided (*id*. at 8:67). The PTFE yarns were a "plurality of filaments of a first fiber-forming material," and the PET yarns were "a plurality of filaments of a second fiber- forming material" as claimed (*id*. at 9:1-8). The volume fraction of the PTFE, the lubricating yarn, was 49% by volume (Ex. 7 at DMI002636). Further, Dr. Steckel

had tested and evaluated the sutures. Therefore, he had reduced the sutures of claims 1, 8, and 9 to practice at least as early as February 1989.

37. I also note that Dr. Steckel built and tested prototypes in December 1989 (Ex. 7 at DMI002665-67). These prototypes were carrier blends of PTFE and PET yarns that were braided in direct intertwining contact (*id*. at DMI002665). The specific braiding sequence is shown in Dr. Steckel's notebook (*id*.). Similar to the prior PTFE/PET braids, these braids are also within the scope of claims 1, 8 and 9 of the 446 patent. Dr. Steckel evaluated the December 1989 prototypes and noted that the prototypes offered "exceptional handling properties for a braided suture" (*id*.). He also found that these prototypes "ranked better" in "handling properties" and knot-tie down relative to silk and Ethibond (*id*. at DMI002666; Ex. 6 at 235:24-236:10). As he explained, the bending modulus of the composite PTFE/PET suture braid was lower than silk and Ethibond (Ex. 7 at DMI002666-67). This means that the PTFE/PET braid was more flexible than silk and Ethibond. Dr. Steckel further noted that the intrinsic tensile and knot strength of the composite braid were 87 ksi. and 48 ksi. respectively. Based on Dr. Steckel's construction and evaluations, it is my opinion that Dr. Steckel had reduced to practice the claimed invention at least as early December 1989.

38. Arthrex's argues that the inventors of the 446 patent did not actually reduce the invention to practice in February 1989 or prior to the February 19, 1992 filing date of the application. I disagree. The inventors had constructed a suture that they knew would work for its intended purpose.

39. Arthrex argues that the inventors never actually reduced the claimed invention to practice because they did not construct a "sterile" suture. It is my opinion that the inventors had reduced

the claimed invention to practice because the inventors had constructed and tested the claimed suture and knew that it would work as a suture for its intended purpose.

40. I also disagree with Arthrex that sterilization was needed to reduce the claimed invention to practice because sterilization of medical devices including sutures were known processes that date well before the inventors work in 1988. The typical sterilization processes are gamma sterilization and ethylene oxide. Notably, the 446 Patent refers to both types of sterilization (Ex. 4 at 6:21-29). One of ordinary skill in the art would have been aware of both methods of sterilization and the parameters for sterilizing sutures and the materials claimed in the 446 patent. Further, one of ordinary skill in the art between 1988 and 1992 would have known that sterilization under normal conditions would not have had any substantial affect on braid properties, other than sterilization. Thus, there was no need for the 446 patent inventors to sterilize the sutures that they had constructed in order to show that they would work for their intended purpose and to prove the concept of their invention.

41. I further disagree with Arthrex that sterilization was needed to reduce the claimed invention to practice because typically sterilization is done for product commercialization, not proof of concept. A suture designer would generally not sterilize his work unless it was to be tested in the body, or it involved product commercialization. Sterilization is basically a commercialization step that was not needed here to prove the concept of the invention claimed in the 446 patent. Requiring the inventor to sterilize the braided suture constructs would basically require him to make a commercial product and sterilize it in its packaging because typically sutures are sterilized in the packaging. In reality, suture designers do not sterilize suture designs to prove the concept unless the designs have something particular to do with sterilization. Here, the focus was on suture properties, and biological testing was not needed.

42. My opinion is supported by Mr. Grafton's deposition testimony concerning the development of the FiberWire product. Mr. Grafton testified that, after Arthrex tested the prototype suture braid of UHMW PE and PET, Arthrex believed it would work as a suture (Ex. 9 at 57:15-18). Although Mr. Grafton was not sure whether the sutures he tested were sterile or nonsterile (and I know of nothing indicating they were sterile), Mr. Grafton testified that sterilization would not be necessary at this stage of development, because it was only the mechanical features of the suture being tested, not the biological features (*id*. at 60:11-23). Thus, Mr. Grafton's testimony supports my opinion that sterilization is typically not needed to prove the mechanical properties of a braided suture.

43. Arthrex’s argument is contradicted by Arthrex’s and Pearsall’s own practices. I understand that Arthrex tested unsterile sutures when it tested coated and uncoated samples to show that FiberWire’s coating has an effect on FiberWire’s lubricity (*id*. at 149:1-152:8). Arthrex’s engineer who coordinated that testing was aware of the known sterilization techniques (*id*. at 97:5-15). He must not have thought that sterilization could have a “substantial effect” on the braid properties because otherwise he would have tested sterile sutures. If sterilization could have a “substantial effect” on the braid properties, then this casts doubt on the reliability of Arthrex’s test results. Also, Pearsalls issued certificates of conformity on the braids that they made for Arthrex’s FiberWire that describe certain suture properties such as knot strength. Arthrex has submitted these documents to the FDA. But Pearsalls does not sterilize sutures.

IV. Description of Polyethylene In the 446 Patent

44. It is my opinion that the 446 Patent discloses UHMW PE to one of ordinary skill in the art at the time the application for the 446 Patent was filed. The 446 Patent specifically claims “PE.” Further, the 446 Patent expressly describes “polyethylene (PE)” (Ex. 4 at 4:27-30). One of skill in the art would have known that “PE” means “polyethylene” and means all polymers made

from ethylene. PE is the generic name for all types of PE, including UHMW PE. In 1987, the Encyclopedia of Polymer Science and Engineering 2nd edition volume 10 recognized polyethylene as the “common (source-based)” name for all polymers made from ethylene (Ex. 10). Further, the IUPAC officially recognized that PE is the accepted abbreviation for all types of PE (Ex. 11). Thus, one of skill in the art would have known that “PE” or “polyethylene” as used in the 446 Patent means all polymers from ethylene including UHMW PE.

45. The 446 Patent’s description of PE is consistent with all types of PE. The 446 Patent states that in a preferred embodiment the first set of yarns act as lubricating yarns (Ex. 4 at 4:11-12). PE including UHMW PE is a lubricious yarn (Ex. 9 at 52:24-53:1). Cohan shows that one of skill in the art would have known that UHMW PE is a lubricious material because the UHMW PE used in the Cohan article slipped and required complex knot configurations in order to evaluate the material’s knot hold strength. Also, the 446 Patent states that the first set of yarns may be derived from “non-absorbable polymers.” PE including UHMW PE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber forming materials (Ex. 4 at 4:30-32). PE including UHMW PE is a fiber forming material. Therefore, the 446 Patent’s description of PE is consistent with the meaning of PE and does not exclude UHMW PE.

46. My opinion that “PE” as used in the 446 Patent includes UHMW PE is supported by Arthrex’s use of the term “polyethylene.” I note that Arthrex described the UHMW PE used in FiberWire and other sutures as “polyethylene” without specifically calling out that it is UHMW PE (Ex. 12 at ARM002188-89; Ex. 13 at DMI Ex. 343). Also, I note that Cohan refers to ultrastrong polyethylene in the first instance but thereafter Cohan uses the terms ultrastrong polyethylene and polyethylene interchangeably to describe the suture materials. Further, my

opinion that one of skill in the art would understand PE to include UHMW PE is confirmed by the DSM brochure. The brochure teaches that "polyethylene" properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus. It also notes that Dyneema SK60 falls within this range at 2.7 N/tex and 90 N/tex. Thus, the DSM brochure refers to UHMW PE as polyethylene, and those skilled in the art do in fact refer to UHMW PE as polyethylene, just as the inventors did in the 446 Patent.

47. My opinion is further supported by the prosecution history of the 446 patent. The Burgess reference discloses high molecular weight polythene (Ex. 14 DMI000123 at line 13-14). During the prosecution history, Mr. Goodwin referred to the high molecular weight polythene disclosed in Burgess generically as "polythene," which is the English term for polyethylene (Ex. 15 at DMI000064). Likewise, the Examiner twice referred to the high molecular weight polythene disclosed in Burgess generically as "polyethylene" (*id*. at DMI000601). Notably, both the Examiner and the applicants referred to high molecular weight polythene by its generic or common, source-based name.

48. PE includes UHMW PE to one of ordinary skill even if UHMW PE is not specifically named. Anything to the contrary does not make sense. It would assume that the well-accepted definition of PE is wrong and excludes UHMW PE. I know of no change in the well-accepted scientific naming conventions. While some authors may specifically refer to UHMW PE, my experience is that they do so when they want to emphasize the characteristics of UHMW PE as compared to PE. Here, the inventors of the 446 Patent had no reason to specifically refer to UHMW PE. PE was referred to as being lubricous. UHMW PE is lubricous. Therefore, there was no particular reason for the inventors to recite both PE and UHMW PE. Notably, the inventors

referred to other materials such as nylon, aramid, PET, PTFE, PETFE, FEP, and PP generically as well. Therefore, the term PE was not treated any differently than the other materials.

49. I understand that Arthrex incorrectly alleges that a "braid made solely of" the first set of yarns (e.g., PTFE, FEP, PFA, PVDF, PETFE, and PE) is described in the 446 Patent as "'highly pliable'" and the first set of yarns are described in the 446 Patent as "relatively weak" (Arthrex Br. at 11-12). I disagree with both assertions. First, I disagree that the 446 Patent describes the first set of yarns being "weak." The 446 Patent never describes the first fiber-forming yarns as "weak." Instead, the 446 Patent, in one embodiment, describes the first set of yarns as lubricating yarns to "improve the overall pliability or compliance and surface lubricity of the heterogeneous braid" (Ex. 4 at 4:12-14). Notably, in the background of the 446 patent it describes a "highly pliable braid" made from "highly lubricous polymers" in a "traditional manner" as being "relatively weak and unusable" in most cases (*id*. at 2:22-25). This sentence states that:

> "[i]f fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable"

(*id*.). But this is not a description of the highly lubricous material as "weak." Rather, it is a description of a certain braid – a highly pliable braid of just highly lubricous material -- as being weak, which is what one of ordinary skill would expect, because the material will likely slip (Ex. 16). But this sentence refers to braids of "highly lubricous polymers" and does not state that all permutations of the first set of yarns are all necessarily the "highly lubricous polymers" identified in the background. Further, this sentence states that "highly pliable braids can be prepared," but that does not mean that all braids made from the materials are highly pliable because they can have different stiffness characteristics or be heat treated or processed in different ways to make the braids less pliable. Also, the 446 patent says that "in most cases," not

all cases, these braids will be relatively weak. Finally, this sentence only refers to some braids as being weak, not the braided materials as being weak, as Arthrex incorrectly suggests. Thus, contrary to Arthrex's suggestion the 446 patent does not say that all braids made from all of the first fiber forming materials are all necessarily highly pliable or that the materials used to make the braids are "weak." I understand that Mr. Grafton constructed a braid of UHMW PE and had this very problem (Ex. 9 at 51:15-52:20).

50. Arthrex's assertion appears to be based on a misunderstanding of the invention described in the 446 Patent. He appears to equate lubricity with weakness and reads the 446 Patent, as describing braiding a weak yarn with a strong yarn. But this is incorrect. The 446 Patent teaches, among other things, that a lubricious yarn can be braided with another yarn of different properties (e.g., different lubricity, strength) to yield a braid that benefits from the lubricity of the first material and the strength of the second material. One of skill in the art, reading the 446 Patent, would understand that a braid of UHMW PE and PET would benefit from the lubricity of the UHMWPE and the strength of the PET. Arthrex appears to assume that because in some embodiments the 446 Patent describes the first set of yarns as being for lubricity and the second set of yarns being for adding strength, that the first set of yarns must be weak. That is not stated in the 446 Patent. Nor would one of skill in the art read "weakness" into the 446 Patent. For similar reasons, column 2, lines 26-28, of the 446 Patent do not teach that there is a necessarily a tradeoff in which the first set of yarns will somewhat weaken the braid because the increases in pliability from the first set of yarns will outweigh the loss of strength as Arthrex suggests (Arthrex Br. at 11).

51. Arthrex also cites to column 2, lines 31-37 for the proposition that the first set of yarns must be weak. But again this sentence does not state that the first–fiber forming materials will

detract from strength. Rather, it states that it would be desirable for the dissimilar materials (i.e., both the first and second yarns, not just the first yarns) to contribute significantly to enhanced pliability without appreciably sacrificing physical properties. Notably, the sentence only states that it would be desirable not to appreciably sacrifice physical properties, which means that they could be increased or decreased, not that they have to be somewhat weaken as Arthrex suggests. Further, to limit the 446 Patent to this specific desire would be inconsistent with the 446 Patent because it describes the properties much broader than just this one desire (Ex. 4 at 2:49-66).

52. Arthrex also cites to column 8, lines 19-49, for this alleged weakening proposition, but this is to a preferred embodiment of PTFE and PET yarns. This is not a discussion of all embodiments. Thus, it is improper to suggest that the specific embodiments of PTFE, which is known to be relatively weak yarn, would behave the same as other strong yarns such as PE, PP, and PVDF variants.

53. I also disagree with Arthrex's assertion that UHMW PE is not "weak." Although Arthrex refers to yarns as being "weak," it does not describe in what sense they are weak. Thus, I am not sure what Arthrex means by "weak." But, I note that Cohan described the tendency of monofilament UHMW PE to slip and the need for more complex knots when tying UHMW PE. In that sense, UHMW PE could be considered weak. I note that Arthrex made similar statements when applying for its own patent (Ex. 17 at 1:13-20). Arthrex reported in its 234 patent that UHMW PE "does not have acceptable knot tie down characteristics for use in surgical applications" (*id*. at 1:20-21). Thus, with respect to knot hold, knot tie, and knot security UHMW PE may be considered "weak."

54. Arthrex argues that the 446 patent's description of certain braids as being weak, as meaning that a braid material is "weak." But describing a braid as weak is not the same as

describing a material as weak. For example, the 446 patent describes a homogeneous *braid* of a highly lubricious material as being relatively weak, not that the first fiber-forming materials are weak (Ex. 4 at 2:23-29). This is not the same as the individual yarn being weak. Mr. Grafton confirmed this with his experiences during the development of the FiberWire product. I understand that Mr. Grafton had tried making a suture form UHMW PE but failed because the UHMW PE was too lubricious (Ex. 9 at 51:15-52:20). After he was unsuccessful with making a suture from just UHMW PE, Mr. Grafton thought of the idea of braiding UHMW PE yarns with PET yarns in direct intertwining contact (*id*. at 53:8-11). When he explained his idea to Dr. Burkhart, who I understand is a surgeon, Dr. Burkhart described the idea as “killer” (*id*. at 54:6-14).

55. I have reviewed Dr. Brookstein's report concerning the description of the first fiber forming materials and his response to Arthrex’s statements that the 446 Patent describes the first fiber forming materials as "weak." Assuming that he means, "weak" in tensile strength, I agree with Dr. Brookstein that the 446 patent does not describe the first fiber-forming materials as "weak." I have reviewed Exs. J, K, L, M, and N to Dr. Brookstein's report and agree that at least some of the first fiber-forming materials, including at least some PE, PP, PVDF (polyvinylidene fluoride) materials, are not "weak" in tension. This supports my opinion that the first fiber-forming materials are not described as "weak." Therefore, because at least some of the first fiber-forming materials are not "weak" in tension, one of skill in the art between 1988 and 1992 would not have understood the 446 Patent to disclose the first fiber-forming materials as being a group of "weak" materials. Accordingly, one of skill in the art between 1988 and 1992 would have understood the 446 patent to disclose UHMW PE by its reference to the generic name "PE."

56. Further, I was responsible for the extrusion, drawing and heat-setting of polypropylene fibers for sutures and know that polypropylene fibers are not considered "weak" fibers. While I directed suture development at U.S. Surgical we developed, manufactured and sold SURGIPRO 100% polypropylene monofilament sutures. From my own experience, 100% polypropylene monofilament sutures are not considered weak.

57. My opinion that one of ordinary skill in the art would understand PE to include UHMWPE is further supported by Arthrex's FiberWire Instructions for Use. Arthrex specifically refers to FiberWire's UHMW PE as "polyethylene" in its FiberWire instructions for use (Arthrex Br. at Ex. 14). Thus, as Arthrex's instructions for use show, those in the suture field refer to UHMWPE generically as "polyethylene."

58. It is my opinion that UHMW PE, like all PE, is lubricous. I understand that Mr. Grafton agrees (Ex. 9 at 52:24-53:1) because UHMW PE is lubricious, it is my opinion that a braid of UHMW PE would have low internal and external frictional properties that would contribute positively towards handling properties, such as tactile feel and tissue passage.

59. The Burgess reference discloses a fishing line that should have a “braided construction” (Ex. 14 at 1:9). Burgess discloses that some filaments are of “high tensile polythene thread” and other filaments are “polyester and/or nylon” (*id*. at 1:10-11). But Burgess does not disclose what kind of “braided construction” he envisioned, how to construct the braid which he references, nor how to use the materials in the “braided construction” he references. For example, Burgess does not disclose whether the polythene thread should be in the core, whether it should be in the sheath alone, or in the sheath with another material. Nor does Burgess disclose whether the polyester and/or nylon alone should be in the core, whether it should be in the sheath alone, or in

the sheath with another material. At no point does Burgess state that the polythene can be in a sheath with another material such as nylon or polyester.

60. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

9/1/06

Date

Dr. Matthew Hermes

HERMES DECLARATION
EXHIBIT 1

ksu upclose
Kennesaw State University
EXCEEDING EXPECTATIONS

Curriculum Vitae

Matthew E. Hermes, Ph. D.,President
F. V. Hayden Institute
Adjunct Professor, Project Director,
ChemCases.Com
Kennesaw State University,
Kennesaw, GA 30114
770-499-3427(w) , (770)641-9535(h)

Box 775574
Steamboat Springs, CO 80477
(970)879-5739(h)
(970)879-1881(w)

email:hayden@cmn.net

Profile:

Dr. Hermes is a scientist, inventor, biographer, educator and public servant with more than 40 years professional experience. At his best he evaluates patterns of relationships - whether personal, cultural or technical - and synthesizes novel and practical solutions to real-world problems. In addition to serving on the Steamboat Springs, CO Board of Education, he currently:

- writes and publishes new systems of chemical education for university students,
- consults on the processes affecting public education boards,
- writes and initiates business plans for startup enterprises and
- collects and preserves documents detailing 19th century western exploration and mapping.

Recent Accomplishments, 1986-2000:

- **As Corporate Research Scientist, 1986-1994, directed research and development leading to introduction of 1,000+ suture products for United States Surgical Corp. Conceptualized, created and protyped products. Designed, built and operated manufacturing. Holds 29 US Patents**
- Discovered and patented practical methods for stabilizing moisture sensitive fibers against hydrolysis. Invention reduced time to market introduction by five years.
- **Envisioned and patented non-protein polymer systems incorporating unique features of predetermined length, composition and sequence. These distinctive properties in proteins drive all living systems.**
- As Adjunct Professor of Chemistry at Wyoming, developed synthetic methods for structural assembly of polyesters with predetermined sequence. Monodisperse oligomers show protein-like configuration.
- **Completed biography "Enough for One Lifetime, Wallace Carothers, Inventor of Nylon", published by the American Chemical Society March 1996.**

- As Contract Consultant to Colorado Advanced Technology Institute, taught Applied Telecommunications to twelve rural Colorado governments and entities. Actively developing and maintaining four World-Wide-Web Internet sites with over 150 documents. AeRie presentation of Rural telecommunications chosen "Pick of the Week", May 1, 1995 by NCSA. Developed and managed web communications for Dept. of Commerce TIIAP GIS development grant.
- **Marketing resort lodging through Internet connectivity, developing electronic marketing data and plans, 1995-1998. Commercial telemarketeing resulted in $2.25M new business for Yampa Valley, Colorado.**
- Currently, President, F. V. Hayden Institute, educational and scientific Institute distributing applied telecommunications to the rural west. Vice-President, CyberCastles, Inc., telecommunciations marketing in the Rural West.
- **Project Director, ChemCases.Com, National Science Foundation-funded University General Chemistry curriculum development project. Written and published two ChemCases. Currently Adjunct Professor of Chemistry, Kennesaw State University, Kennesaw, GA.**
- Elected to Steamboat Springs, Colorado RE-2 Board of Education, 1997.
- **Completed digitizing the 1881 "Atlas of Colorado". Produced CDROM of maps and western art as educational and recreactional resource for the US Forest Service.**
- Consultant in public board of education "policy governance" with Aspen Group International.

Recent United States Patents:

4,744,365(1988) Compositions for Absorbable Surgical Devices
4,839,130(1989) Process of Absorbable Surgical Device
4,844,854(1989) Process for Making a Surgical Device Using Two-Phase Compositions
5,019,093(1991) Braided Suture
5,037,429(1991) Improving the Stability of Braided Sutures
5,051,272(1991) Improving the Stability of a Polymeric Article
5,124,103(1992) Two Phase Compositions for Absorbable Surgical Devices
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5,226,912(1993) Combined Surgical Needle-Braided Suture Device
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5,256,762(1993) Polyesters of Predetermined Monomeric Sequence
5,261,886(1994) Cabled Core and Braided Suture Made Therefrom
5,282,829(1994) Hollow Body Implants
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5,366,081(1994) Packaged Synthetic Surgical Suture Elements
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5,447,966(1995) Coating Surgical Articles
5,456,697(1995) Cabled Core and Braided Suture Made Therefrom
5,462,162(1995) Packaged Synthetic Absorbable Surgical Elements
5,468,252(1995) Packaged Synthetic Absorbable Surgical Elements
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5,475,063(1995) Polymer Blends

Recent Publications:

- ChemCases.com in the Classroom, American Chemical Society meeting, San Francisco, CA, March 30, 2000
- ChemCases Modular Curriculum as Distance Learing Tool, American Chemical Society Meeting, Anaheim, CA, March 23, 1999
- Gatorade as Case Study Curriculum Supplement, American Chemical Society Meeting, Dallas, TX, April 2, 1998.
- Gatorade, Why We Drink that Pale Yellow Stuff, Presentation at Kennesaw State University, Sept. 30, 1997.
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- The Ineluctable Fate of Carothers, Chemistry and Industry, April 15, 1996
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- Wallace Carothers, Inventor of Nylon, Presentation to the San Francisco Psychobiography Group, Jan. 14, 1993.
- Wallace Carothers, Inventor of Nylon, Presentation to the Wyoming Section of the American Chemical Society, April 27, 1993.
- Polyesters of Predetermined Sequence, with Dr. Bin Huang, Journal of Polymer Science, Vol. 33, p.1419(1995).

Career Profile:

Education:

- B. S. Chemistry, St. John's University, Brooklyn, NY, 1955.
- Ph. D., Chemistry, University of Maryland, 1959.
- M. A., Liberal Studies, Wesleyan University, 1992.

Employment History:

- Research Chemist, Supervisor, E. I. DuPont, 1959-79.
- Research Director, Virginia Chemicals, Celanese Co., 1979-83.
- Corporate Research Scientist, U. S. Surgical Corp., 1983-94.
- Adjunct Professor, University of Wyoming, 1992-1994
- Consultant, Colorado Advanced Technology Institute, 1995-7

- President, F. V. Hayden Institute, 1996-present
- Adjunct Professor, Kennesaw State University, 1997-present

Early Accomplishments, 1955-1983:

- With Prof. William Bailey at Maryland, produced monomers and polymers demonstrating polymerization through Diels-Alder polymerization.
- At DuPont Central Research, discovered the chemistry of the treacherously explosive cyanogen azide. Developed safe handling methods and described mechanism of ring-chain tautomerisms and skeletal rearrangements.
- At DuPont solved the thirty-year problem of moisture degradation of abrasion resistant coatings for transparent acrylic sheet.
- At Virginia Chemicals, unraveled mystery of large industrial explosion and rationilized thermochemistry of the inorganic paper chemical, sodium hydrosulfite.

Early Publications:

W. J. Bailey, M. E. Hermes et al., Journal of Organic Chemistry, 27,1975(1962)
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M. E. Hermes and R. A. Braun, Journal of Organic Chemistry, 31,2568(1966)
M. E. Hermes and F. D. Marsh, Journal of the American Chemical Society, 89,4760(1967)
M. E. Hermes and F. D. Marsh, Journal of Organic Chemistry, 37,2969(1972)

Early United States Patents:

3,642,681(1972) Polysilicic Acid Coatings
3,714,214(1973) Alkoxy Silyl Alkyl Compounds
3,775,171(1973) Article Coated with Polysilicic Acid
3,781,251(1973) Alkoxy Silyl Alkyl Compounds and Polymers

Personal

Single, Excellent Health.
Director, Steamboat Springs RE-2 School Board; Secretary, Steamboat Springs Education Fund Board; Steamboat Springs Kiwanis; American Chemical Society.

04/7/00

HERMES DECLARATION
EXHIBIT 2

US005318575A

United States Patent [19]

Chesterfield et al.

[11] Patent Number: 5,318,575

[45] Date of Patent: Jun. 7, 1994

[54] METHOD OF USING A SURGICAL REPAIR SUTURE PRODUCT

[75] Inventors: Michael P. Chesterfield, Norwalk; Ilya Koyfman, Orange, both of Conn.

[73] Assignee: United States Surgical Corporation, Norwalk, Conn.

[21] Appl. No.: 829,423

[22] Filed: Feb. 3, 1992

[51] Int. Cl.[5] A61B 17/00

[52] U.S. Cl. 606/151; 606/228; 606/231; 128/898; 623/13

[58] Field of Search 606/228, 231, 151; 623/13; 128/898

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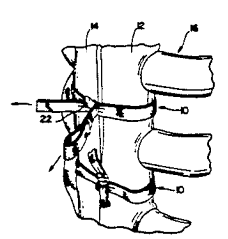
(List continued on next page.)

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—J. A. Schmidt

[57] ABSTRACT

Textile surgical articles are disclosed which are constructed in whole or in part from high tenacity low elongation fibers such as ultra-high molecular weight extended chain polyethylene high tenacity fibers. The products may be braided, woven or knitted, such as braided tapes, hollow braids and spiroid braids. The high tenacity low elongation fibers provide structures having greatly increased strength and decreased elongation, a combination of properties which is uniquely applicable and superior for repairing body tissue. The products may be plasma treated to reduce slip.

12 Claims, 2 Drawing Sheets



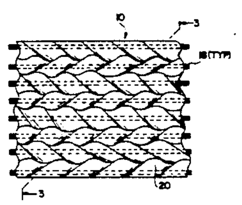


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FIG. 1

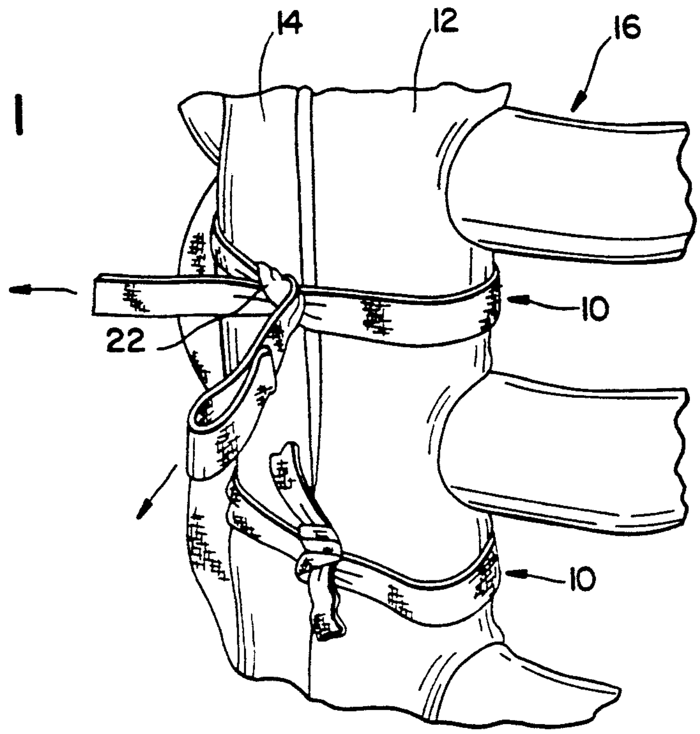
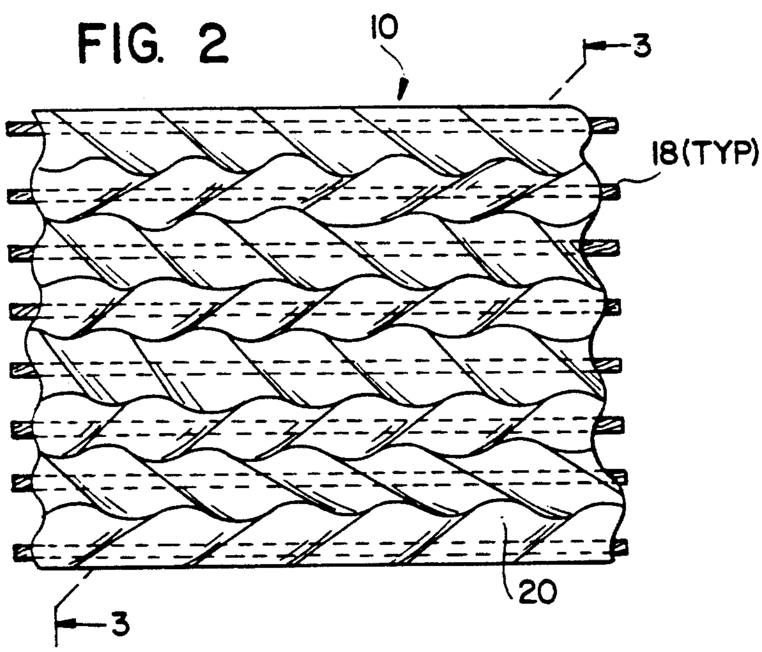


FIG. 2



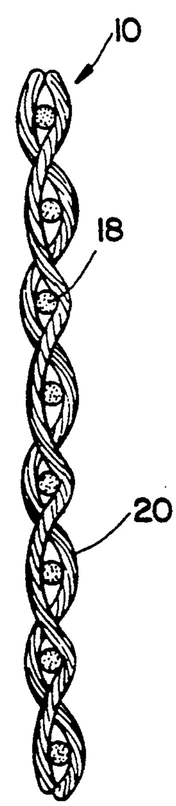


FIG. 3

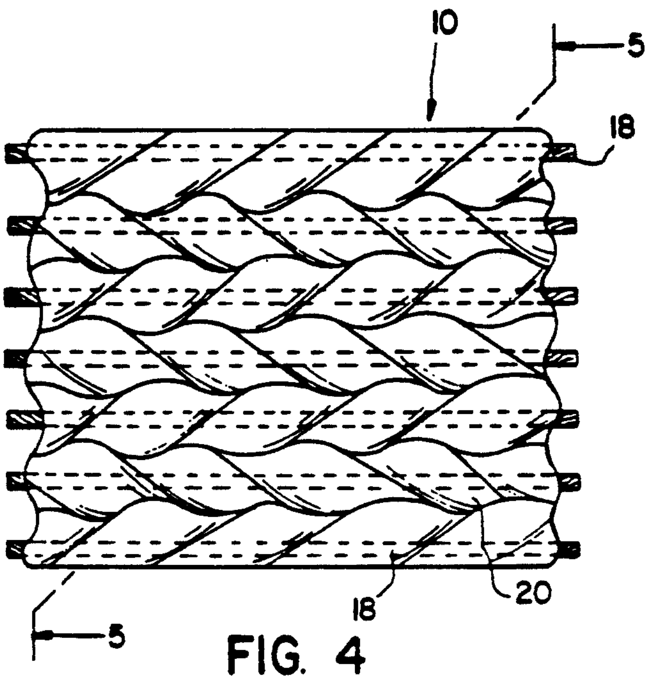


FIG. 4

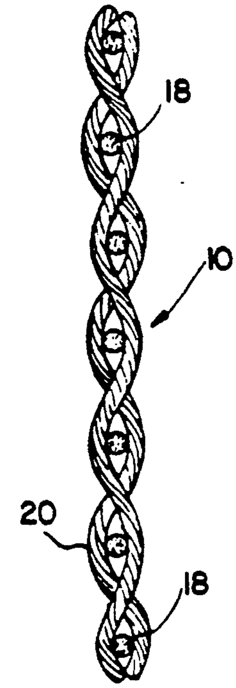


FIG. 5

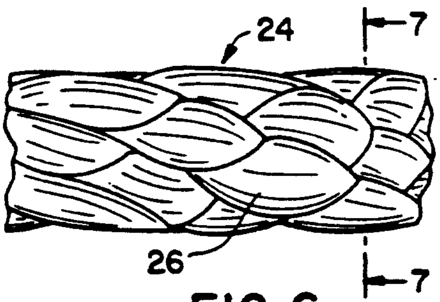


FIG. 6

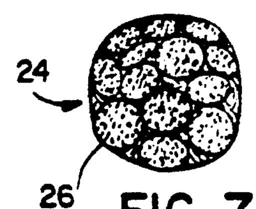


FIG. 7

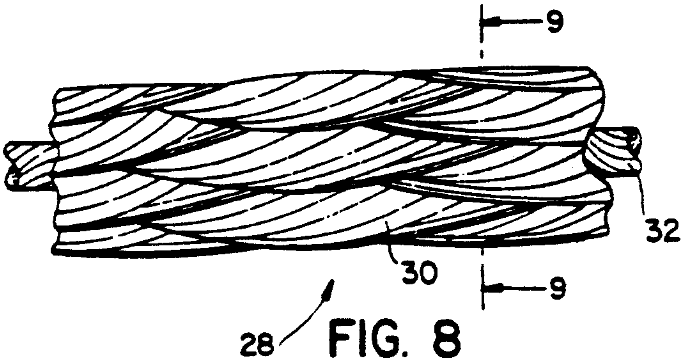


FIG. 8

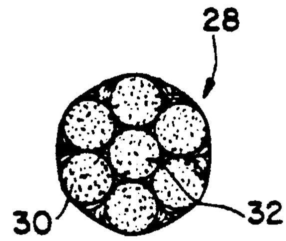


FIG. 9

METHOD OF USING A SURGICAL REPAIR SUTURE PRODUCT

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to suture products for surgical repair of body tissue. In particular, the invention is directed to reinforced surgical repair products for repairing the human sternum after surgery.

2. Background of the Prior Art

Presently there are many known products for repairing human body tissue in areas where a repair may be required either as a result of an injury or during or after surgery. In particular, it is well known to utilize suture products in the form of elongated strands to repair human body tissue as well as utilizing two-part fasteners or metal staples for attaching body tissue after portions have been removed during surgery.

For example, sutures intended for repairing soft body tissue are usually constructed of a plurality of filaments and applied to the tissue with any number of surgical needles. More recently, a certain amount of emphasis as been placed upon repairing surgical bone utilizing an elongated surgical product either in the form of a flat band or in the form of a strand having the construction similar to a suture by simply utilizing a needle to penetrate the bone to apply the repair product to the bone in a manner which physically retains the separated bone portions together to promote permanent healing. One such example is disclosed in U.S. Pat. No. 4,535,764 to Ebert which relates to a surgical bone tie having a needle connected to one end of a band such that the band may be looped and arranged to be appropriately looped around the bone portions requiring repair.

U.S. Pat. No. 4,813,416 relates to a band assembly and method for sternum closing with which the sternum halves are brought to abutting closure utilizing a band having a needle at one end to facilitate looping the band in position to retain the sternum portions in adjacent butting contacting relation.

Numerous other products have been used to retain bone portions together to promote healing while numerous suture products have been used to retain soft tissue to retain healing.

While many attempts have been made to provide such products little emphasis has been applied to the physical strength characteristics of the components which form the actual suture or band product in order to provide the surgeon with precision control on the product. Moreover, control is required on the tissue to which the product is applied in a manner which will promote healing of the tissue, yet will not cause unnecessary cutting of the tissue when force is applied to the product and the force is in turn applied to the tissue.

A particularly desirable product for accomplishing these goals would preferably display substantial strength without significant elongation to facilitate retaining the tissue portions together. In the case of attaching separate bone portions of the sternum together after open heart surgery for example, it has been necessary to utilize metal wire filaments by looping the wire filaments around the sternum portions and actually twisting the filament ends together to form an attachment. The metal wire displayed sufficient strength to retain the bone portions together without elongation. However, the wire represented a relatively sharp nonabsorbable foreign body which remains embedded

within the body tissue and thus presents a potential source of infection or other complications as a result of its presence within the body. Moreover, the relatively sharp characteristics of the wire present a danger of cutting into the bone during the application to the sternum. The sharp wire also presents a hazard to the surgeon and operating room personnel in that the wire may penetrate surgical gloves and cut the surgeon or attendant personnel, thereby creating a potential site for transmission of disease.

While utilization of wire sutures has been used and accepted during open heart surgery there remains room for improvement in the products used for strapping the split sternum portions together. Desirably, it would be best to provide a known metallic product which not only provides the strength to elongation characteristics of the metal sutures but which may be utilized to form a tying product for soft as well as hard tissue, in a manner which will minimize the dangers of cutting of the tissue in the surrounding areas. The present invention is directed to such a product.

SUMMARY OF THE INVENTION

In accordance with the present invention, textile surgical articles are disclosed which are made in whole or in part from high tenacity low elongation fibers such as ultra high molecular weight extended chain polyethylene high tenacity fibers. One such fiber is Spectra yarn from Allied Signal Corp. The products may be braided, woven or knitted, although braided tape, hollow braids and spiroid braids are preferred. The high tenacity low elongation fibers provide structures having greatly increased strength and decreased elongation.

In one embodiment, braided tapes are made from Spectra yarn. In an alternative embodiment braided tapes are made with Spectra runners and bioabsorbable, Dacron polyester and/or nylon fill yarns.

Further alternative embodiments include tubular braided structures having a core made in whole or in part from high tenacity low elongation fibers or spiroid braided structures made in whole or in part from high tenacity low elongation fibers.

In a preferred method of the invention, a braided tape reinforced with ultra-high molecular weight high tenacity fibers is used to join a divided sternum by tying, or other appropriate means. The tape has a very high strength, preferably equal to or greater than 35 kg. straight pull and more preferably greater than about 50 kg. straight pull, and low elongation at break, preferably below about 20%, more preferably below about 10 to 15%, and most preferably below about 5%.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described hereinbelow wherein:

FIG. 1 is a perspective view of a portion of a split human sternum illustrating one application of the present invention for retaining the split portions together to promote healing;

FIG. 2 is an enlarged view of the suture product shown in FIG. 1 illustrating one embodiment wherein the elongated product is a flat braided member and contains at least eight reinforcing filaments extending along the length;

FIG. 3 is a cross-sectional view taken along lines 3—3 of FIG. 2.;

FIG. 4 is an enlarged view of an alternative embodiment of the suture repair product of FIG. 2 wherein the elongated braided product contains at least seven reinforcing filaments extending along the length;

FIG. 5 is a cross-sectional view taken along lines 5—5 of FIG. 4;

FIG. 6 is a view of an alternative embodiment of the suture repair product wherein the elongated member is a spiroid braided member having a generally circular cross-section containing at least one elongated reinforcing member;

FIG. 7 is a cross-sectional view taken along lines 7—7 of FIG. 6;

FIG. 8 is a view of another alternative embodiment of the suture repair product wherein the elongated product is a hollow braided member having a generally circular cross-section and contains at least one elongated reinforcing member extending centrally thereof along the length; and

FIG. 9 is a cross-sectional view taken along lines 9—9 of FIG. 8.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to FIG. 1 there is illustrated a sternum closure ribbon 10 constructed according to the present invention and positioned to retain portions 12,14 of a human sternum 16 together. The band 10 is preferably a braided product as shown in FIGS. 2 and 4 having a plurality of elongated filamentary reinforcing members of ultra high molecular weight polyethylene fibers. The fibers may be plasma treated to reduce slip characteristics of the yarn, if desired. In particular, such fibers as extended chain polyethylene high tenacity fibers (ECPE) marketed under the trademark SPECTRA® by Allied-Signal Technologies, Petersburg, Va. 23804 are preferred as reinforcing members provided in the product of the present invention. SPECTRA 1000 yarn is suitable. These extended chain fibers exhibit a molecular weight generally between about 1 million to about 5 million but also may be as low as 500,000. They exhibit a very substantial degree of crystalline orientation (95–99%) and crystalline content (60–85%). As a result the fibers exhibit strengths from about 375 kpsi (thousands of pounds per square inch) to about 560 kpsi and tensile moduli of from about 15 msi (millions of pounds per square inch) to about 30 msi. The significant strength and stability of these fibers are caused by the high degree of molecular orientation. Moreover, since the fibers can be provided as multifilament or monofilament fibers which can be braided, woven, knitted or otherwise processed to form a textile product it will be readily appreciated that any number of reinforced textile products may be provided similar to the band 10 shown in the drawings, but with numerous alternative applications as will be described hereinbelow.

Referring now to FIG. 2, the band 10 shown in FIG. 1 is shown in greater detail as an elongated flat braided textile product having a plurality of high molecular weight fibers 18 extending along the length of the band.

The elongated fibers 18 are preferably made of ECPE marketed under the SPECTRA® trademark and are surrounded by braided fibers 20 which may be of the bioabsorbable type. For example, fibers 20 may be made of any suitable bioabsorbable polymeric material such as polymers or copolymers of glycolide, lactide, p-dioxanone, polyester, polyamino acids and the like as disclosed in U.S. Pat. Nos. 2,668,162; 3,297,033; 3,636,956; 3,736,646; and 3,839,297. The number of reinforcing filaments 18 included in the braided band 10 shown in FIG. 2 is optional as is the specific construction of the band. For example, as seen in FIG. 4, there is an example of an alternative braided band construction having seven reinforcing filaments 18 of high molecular weight, high strength fibers of the type shown in FIG. 2. Furthermore, as seen in FIG. 7, there is an alternative elongated embodiment of spiroid braided construction of generally circular cross-section and comprised of one or more elongated filaments 26 of high molecular weight, high strength, with the remainder of the braid being of bioabsorbable filamentary materials to form a braided rope-like construction of generally circular cross-sectional configuration as shown in FIG. 7. Alternatively the braided product 22 may be constructed entirely of such high molecular weight, high strength, elongated filaments 24. Braid constructions having a circular cross-section are described in U.S. Pat. Nos. 3,565,077 and 5,019,093. Any number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated, depending upon the intended application.

In FIGS. 8 and 9 there is shown a hollow braid construction 28 having a sheath constructed of bio-absorbable yarns 30 and having a core 32 of high molecular weight, high strength filament. Any number of alternative combinations of 0 to 100% absorbable filamentary or otherwise, and/or non-absorbable yarns and high strength filaments are contemplated depending upon the intended application.

It will be appreciated that in addition to the examples which follow hereinbelow, numerous alternative textile constructions may be incorporated into the present invention to form a reinforced band for attaching body tissue such as a soft tissue or bone tissue without suffering from the disadvantages from presently known materials. For example, it is conceivable within the scope of the present invention to provide a woven structure containing a plurality of elongated high strength filaments 18 in the warp direction wherein the filler yarns are of a suitable bioabsorbable material such as polymers or copolymers of glycolide, lactide, p-dioxanone, polyester, polyamino acids and the like, or with fill yarns of a nonabsorbable material such as Dacron polyester or nylon. Likewise, knitted structures may be strengthened by reinforcement with high tenacity fibers. It will be appreciated that in each of the embodiments discussed herein the strength characteristics of the high tenacity, low elongation fibers 18 will provide the substantial force carrying capability to the elongate product while the fibers 20 surrounding the high strength filaments will provide the necessary structural support to the main fibers for forming the product. The surrounding fibers will also define the "hand" or "feel" of the band.

Accordingly, it is possible in one application to position the reinforced structure 10 about the split portions 13,14 of the human sternum 16 as shown in FIG. 1 whereby substantial force may be applied to the band by tying the band either by a knot 22 shown in FIG. 1, or by other techniques whereby significant force may be applied and retained to promote natural healing of the sternum portions 12,14, e.g. mechanical connecting devices such as buckles, etc. See, for example, U.S. Pat. No. 4,813,416. It has been found that such a band has a strength to elongation ratio comparable to stainless

steel. The strength and load carrying capability of the elongated filaments **18** is sufficient to transmit substantial force to the sternum with minimum elongation occurring to the fibers thereby permitting the sternum portions to undergo a natural healing process. Furthermore, in addition to the textile processes of braiding and weaving it should be noted that alternative textile processes may be utilized including knitting techniques, provided that the final product contains a plurality of elongated high strength filaments **18,22** extending along at least the length of the product in the force-carrying direction to maintain the tissue portions together.

The braided product also may be made on a so-called spiroid braider by a method whereby a plurality of filament dispensers are moved in the same direction to different positions around a closed loop. In addition, the braid product may be produced by a conventional braiding process by directing a plurality of yarn dispensers along in equal and opposite undulating paths while directing the filaments or filler fibers toward a common braiding zone. In either process the final braided product will be manufactured to include a plurality of high strength, high molecular weight, high tenacity filaments as disclosed hereinabove, either as a component of the product, e.g. a core, or as the sole material used to construct the product. In addition, the yarn and/or product may be plasma treated depending upon the particular needs or intended application so as to reduce the perceived "slipperiness" of the product as desired.

For example, in any of the braided products disclosed herein the portions of the yarns may be of such high molecular weight, high tenacity filaments while the remaining portions are of absorbable or non-absorbable fibers or filaments. Further, the yarns may also be entirely of such high molecular weight, high tenacity filaments. For such products containing a core, the core may be as noted above, in combination with various types of fibers and/or filaments, absorbable or non-absorbable as described herein.

The final product could be provided with a surgical needle at one or both ends to facilitate insertion of the product into the body tissue whether the body tissue be soft skin tissue or hard bone tissue, or the needles may be utilized to facilitate looping the product into and out of spaces formed between the component members of the body such as the components forming the human sternum. Alternatively, the product could be provided with a needle at each end to facilitate ease of application to the body portions. In either event, the strength and the load carrying filaments **18** and the minimal elongation to strength percentage renders such filaments ideal for incorporation into a final product wherein body portions can be retained together to promote healing. In particular, the formation of a surgical suture repair product utilizing textile processes in combination with bioabsorbable filaments renders the incorporation of high tenacity, high strength, high molecular weight filaments **18** as an ideal combination to form a surgical suture repair product.

The following examples are provided for flat tapes and braids which can be utilized to tie two half portions of a human sternum to promote healing. In the examples which follow, all tapes or braids use Dacron polyester yarn. Braiding of the tapes or braids with Dacron yarns are noted for exemplary purposes only and such yarns may be appropriately substituted with any other suitable bioabsorbable or nonabsorbable yarns, as desired or appropriate for a particular construction. Of course, substitution of different yarns may require variations to the structure as required to accommodate changes in density and/or fiber denier. The fibers may be twisted or air entangled periodically to create a false twist.

EXAMPLE 1

A braided tape of Spectra 1000 high tenacity polyethylene multifilament fibers (60 filaments, 215 denier) was made on a 15 carrier flat tape braider with 7 parallel runners. This structure is shown in FIGS. **4** and **5**. Tests showed the following properties.

Denier =	10,585
Tape Thickness =	0.66 mm
Tape Width =	3.91 mm
Knot pull =	47.5 kg
Straight pull =	66.5 kg
Pick count =	20 crossovers per inch

The tape of this example was made with air entangled rather than twisted yarn. It is contemplated that the yarn could instead be twisted prior to braiding, with all or some of the yarn twisted in either the "s" or "z" directions. Twisted yarn should increase strength and decrease slipperiness of the tape.

EXAMPLE 2

A braided tape having multifilament Spectra 1000 runners (60 filaments, 215 denier) and Dacron fill yarns was made on a 17 carrier braider with 8 parallel runners. This structure is shown in FIGS. **2** and **3**. The Dacron fill yarns were made with three plies of air entangled 100 denier, 54 filament Dacron type 55 yarn. The properties of the tape were measured as follows:

Denier =	7,551
Tape Thickness =	0.34 mm
Tape Width =	3.14 mm
Knot pull =	36.5 kg
Straight pull =	53.6 kg
Elongation at break =	3.4%
Pick count =	26 crossovers per inch

EXAMPLE 3

A braided tape is made with Spectra 1000 runners (60 filaments, 215 denier) and nylon fill yarn. The nylon fill yarn is made from three plies of 100 denier, 34 filament type 385 Dupont bright air entangled nylon yarns. The tape may be made to the desired width, thickness and pick count on any appropriate braider, such as a 15 carrier braider with 7 runners or a 17 carrier braider with 8 runners or a 21 carrier braider with 10 runners.

EXAMPLE 4

A braided tape is made with Spectra 1000 runners (60 filaments, 215 denier) and a bioabsorbable fill yarn such as a yarn made from a copolymer of glycolide and lactide. The bioabsorbable fill yarn may be twisted or air entangled and plied to a total denier of about 300 denier. the tape may be made to the desired width thickness and pick count on any appropriate braider, such as a 15 carrier braider with 7 runners or a 17 carrier braider with 8 runners or a 21 carrier braider with 10 runners.

EXAMPLE 5

A braided tape of plasma treated spectra 1000 high tenacity polyethylene multifilament fibers (60 filaments, 215 denier) was made on a 15 carrier flat tape braider with 7 parallel runners. Tests showed the following properties:

Denier =	5,338
Tape Thickness =	0.40 mm
Tape Width =	3.21 mm
Knot pull =	47.5 kg
Straight pull =	66.5 kg
Elongation at break =	8.6%
Pick count =	25 crossovers per inch

The tape of this example was made with air tangled rather than twisted yarn. It is contemplated that the yarn could instead by twisted prior to braiding, with all or some of the yarn twisted in each of the "s" or "z" directions.

The tape made from plasma treated yarn was perceptibly less slippery than the tape of Example 1, which may be desirable under some circumstances.

EXAMPLE 6

A suture of spiroid braid construction was made on a 15 carrier spiroid braider using Spectra 1000 yarn (60 filament, 215 denier). The braid is shown in FIGS. 6 and 7. The braid had the following properties.

Denier =	3,248
Diameter =	0.832 mm
Knot pull =	32.4 kg
Straight pull =	43.0 kg
Elongation at break =	14%

Spiroid sutures may be made with twisted yarn with a variety of carriers, such as 9, 12, 20 or 25 carriers, as desired to obtain a particular configuration.

EXAMPLE 7

A suture of hollow braid construction having a Spectra 1000 core was made, and is shown in FIGS. 8 and 9. Dacron air entangled bright polyester yarn (40 denier, 8 filament, type 55) was used on the carriers of an 8 carrier braider (4 carriers travelling in the S direction, 4 carriers travelling in the Z direction) to make a sheath surrounding a core of untwisted Spectra 1000 yarn. The properties of the suture were as follows.

Denier =	550
Diameter =	0.20 mm
Knot pull =	3.9 kg
Straight pull =	7.9 kg
Elongation at break =	3.3%

A wide variety of hollow braid constructions are contemplated. Thus, sutures having Spectra 1000 core or components can be made on braiders having 12, 16, 24, 28 or 32 carriers, and numerous yarns can be used to form a sheath surrounding the core, such as bioabsorbable yarn; Dupont Dacron polyester air entangled bright yarn (such as 100 denier, 54 filament type 55 bright yarn or 70 denier, 34 filament type 52 bright yarn); or Dupont air entangled nylon yarn (such as 40 denier, 13 filament type 335 bright yarn or 100 denier 34 filament type 385 bright yarn or 70 denier, 34 filament type 185 bright yarn or 55 denier 17 filament type 865 bright yarn, or 15 denier 7 filament type 180 bright yarn).

The core yarns may be twisted to condense the structure or plied to increase strength and denier. The sheath yarns may also be twisted, if desired.

In the foregoing examples, all physical tests were conducted at 73° F., 50% relative humidity on an Instron Corporation Model 4502 test apparatus. Knot pull tests were performed using a 6 inch gauge length with a 0.5 inch per minute crosshead speed. Straight pulls were made using a 10 inch gauge length with a 10 inch per minute crosshead speed. Yarn or tape grips were used, as appropriate.

While the foregoing description contains many specifics, it will be understood that numerous modifications may be made within the scope of the appended claims. By way of example, a wide variety of yarn substitutions may be made to arrive at various braided tape or hollow and spiroid suture configurations constructed in whole or in part from high tenacity reinforcing fibers. In addition, bioabsorbable and non-bioabsorbable yarns may be substituted as desired to achieve properties and characteristics suitable for a particular situation.

We claim:

1. A method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue in a manner to attach the portions in adjacent engaged relation to promote natural healing thereof, said flexible member being formed at least in part of first fibers of ultra-high molecular-weight high tenacity material and at least second fibers which differ from said first fibers and are formed from a non-absorbable material, said first and second fibers being braided to form said elongated member.

2. The method of claim 1 wherein the molecular weight of said fibers is within the range of from about 500,000 to about 5 million.

3. The method of claim 2 wherein said fibers comprise high tenacity extended chain polyethylene fibers.

4. The method of claim 1 wherein said elongate member has an elongation to break below about 15%.

5. The method according to claim 1 wherein said elongate member is of a flat braided construction.

6. The method according to claim 1 wherein said elongate member is of hollow braid construction.

7. The method according to claim 6 wherein said hollow braid contains a core.

8. The method according to claim 1 wherein said elongated member is of spiroid braid construction.

9. The method according to claim 8 wherein said spiroid braid has a substantially circular cross-sectional shape.

10. The method according to claim 1 wherein said elongated member has a straight pull greater than about 35 kg.

11. The method according to claim 1 wherein said second non-absorbable fibers are formed from nylon.

12. The Method according to claim 1 wherein said second non-absorbable fibers are formed from polyester.

* * * * *

HERMES DECLARATION
EXHIBIT 3

#9

OIPE JC141 JUN 04 2003 PATENT & TRADEMARK OFFICE

Docket No.: A8130.0013/P013
(PATENT)

Andrew S. Boyce 6/11/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
R. D. Grafton

Application No.: 09/950,598

Group Art Unit: 3731

Filed: September 13, 2001

Examiner: G. Phanijphand

For: HIGH STRENGTH SUTURE MATERIAL

AMENDMENT

RECEIVED
JUN 1 0 2003
TECHNOLOGY CENTER R3700

Box Non-Fee Amendment
Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the Office Action dated March 12, 2003, please cancel claim 4, amend claims 1, 3, 5-6, 8-9, and add new claim 10 in the above-identified U.S. patent application as shown in the Section marked "Amendment to the Claims".

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI041087

1569170 v1; Y9X801!.DOC

Application No.: 09/950,598 Docket No.: A8130.0013/P013

AMENDMENTS TO THE CLAIMS

1. (amended) A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. (original) The suture filament of claim 1, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. (currently amended) The suture filament of claim 1, wherein the polyester comprises about 40% of the braided ~~filaments~~ fibers.

a1

4. (canceled)

4 ~~5~~. (currently amended) The suture filament of claim 1 ~~4~~, wherein the core comprises about 30% of the filament.

5 ~~6~~. (currently amended) The suture filament of claim 1 ~~4~~, wherein the cover comprises about 70% of the filament.

6 ~~7~~. (original) The suture filament of claim 1, further comprising a coating disposed on the cover.

8 ~~8~~. (currently amended) A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester~~, and~~;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI041088

Application No.: 09/950,598 Docket No.: A8130.0013/P013

9. (currently amended) A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester~~, and~~;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

A' Cancl 7 ~~10~~. (new) The suture filament of claim 1, wherein the polyester is non-absorbable.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI041089

Application No.: 09/950,598 Docket No.: A8130.0013/P013

REMARKS/ARGUMENTS

Claims 1, 3, 5, 6, 8, and 9 have been amended. Claim 4 has been canceled. Claim 10 has been added. Accordingly, claims 1-3 and 5-10 presently are pending.

Claims 1 and 4-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,045,571 to Hill et al. Claims 1 and 4-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,318,575 to Chesterfield et al. Claim 7 stands rejected under 35 U.S.C. § 103 as being unpatentable over Chesterfield et al. in view of U.S. Pat. No. 4,047,533 to Perciaccante et al. Applicant respectfully traverses the prior art rejections.

The present invention as recited in amended claim 1 is a suture filament suitable for use as a suture or ligature. The suture filament includes a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester, and a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

In contrast to the present invention, Hill et al. discloses a surgical cord having a braided core. According to the disclosure of Hill et al., twisted cores are disadvantageous. Consequently, Hill et al. discloses cores formed of interlocking yarns, "as distinguished from twisted" cores. Instead of being twisted, the core yarns are "interlocked" by braiding or knitting. Thus, Hill et al. does not disclose or suggest the present invention, but rather teaches away from the present invention having a twisted core. Further, Hill et al. does not disclose suture made of ultrahigh molecular weight polyethylene. On the contrary, Hill et al. discloses polyethylene terephthalate (PET) in the molecular weight range of 30,000 to 45,000, and isotactic polypropylene homopolymer having a weight average molecular weight of from about 260,00 to about 420,000. Hill et al. does not discuss ultrahigh molecular weight polyethylene. Claim 1, and its dependent claims 2, 3 and 5-7 are submitted as being patentable over Hill et al.

Chesterfield et al. '575 discloses various surgical constructs that utilize ultrahigh molecular weight polyethylene, but does not disclose the invention recited in the claims as

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI041090

presently amended. The Examiner refers to Figs. 2 and 3 and associated text from the Chesterfield et al. '575 patent, but applicant notes that these figures disclose a band 10, in contrast to the suture filament having a core and a cover as recited in claim 1 of the present application. Applicant notes further that none of the examples disclosed in the Chesterfield et al. '575 patent provides a suture having an UHMWPE core surrounded by a braided sheath or cover that includes a blend of both UHMWPE and polyester. On the contrary, the suture construction of Example 6 of Chesterfield et al. '575 has no core. The suture of Example 7 of Chesterfield et al. '575 uses a Spectra 1000 core surrounded by a hollow braided sheath made of a single type of yarn. See col. 7, line 61 to col. 8, line 5. Applicant respectfully submits that Chesterfield et al. '575 does not anticipate the present invention as recited in amended claim 1.

Claims 2 and 3 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chesterfield et al. Applicant respectfully traverses the prior art rejections.

Claims 2 and 3 of the present invention contain limitations regarding percentages of UHMWPE and polyester in the braided fibers of the suture cover. As noted above, Chesterfield et al. '575 does not disclose an example of a braided sheath that includes a blend of both UHMWPE and polyester. Consequently, it appears that the motivation for selecting a particular percentage by which the fibers are blended comes only from applicant's disclosure. Further, the Office action lacks evidence supporting the Examiner's contention regarding the knowledge in the art on varying the composition of a suture. Dependent claims 2 and 3 are submitted as being patentable over the cited references.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chesterfield in view of U.S. Pat. No. 5,720,765 to Thal. Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chesterfield et al. in view of U.S. Pat. No. 6,063,105 to Totakura. Applicant respectfully traverses the prior art rejections.

The present invention as recited in claim 8 is a suture assembly including a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI041091

molecular weight polyethylene and fibers of polyester, and a core formed of twisted fibers of ultrahigh molecular weight polyethylene. A suture anchor is attached to the suture. Claim 9 recites a suture assembly having suture with a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester, and a core formed of twisted fibers of ultrahigh molecular weight polyethylene. A half round, tapered needle is attached to the suture.

Chesterfield et al. '575 discloses various surgical constructs that utilize ultrahigh molecular weight polyethylene, but does not disclose the invention recited. As noted above, the Office action refers to Figs. 2 and 3 and associated text from the Chesterfield et al. '575 patent, but these figures disclose a band 10, in contrast to the suture filament having a core and a cover as recited in claims 8 and 9 of the present application. Also, none of the examples disclosed in the Chesterfield et al. '575 patent provides a suture having an UHMWPE core surrounded by a braided sheath or cover that includes a blend of both UHMWPE and polyester. On the contrary, the suture construction of Example 6 of Chesterfield et al. '575 has no core. The suture of Example 7 of Chesterfield et al. '575 uses a Spectra 1000 core surrounded by a hollow braided sheath made of a single type of yarn. See col. 7, line 61 to col. 8, line 5. Applicant respectfully submits that Chesterfield et al. '575 does not disclose the present invention as recited in claims 8 and 9.

The patents to Thal and Totakura have been cited as providing a suture anchor and a half-round, tapered needle, respectively. Neither of the patents discloses or suggests a braided suture having a blended sheath and a twisted core as recited in independent claims 8 and 9 of the present application.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI041092

Application No.: 09/950,598 Docket No.: A8130.0013/P013

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Dated: June 4, 2003

Respectfully submitted,

By

Peter McGee
Registration No.: 35,947
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L Street NW
Washington, DC 20037-1526
(202) 785-9700
Attorneys for Applicant

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI041093

HERMES DECLARATION
EXHIBIT 4

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] Int. Cl.[5] **D04C 1/00**

[52] U.S. Cl. **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

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Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

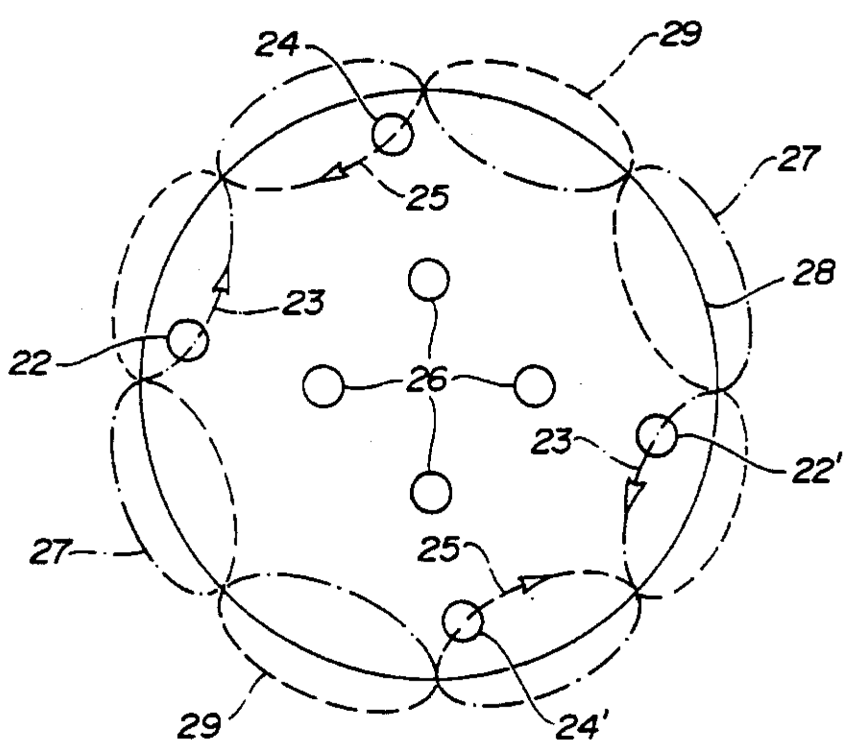


FIG-2

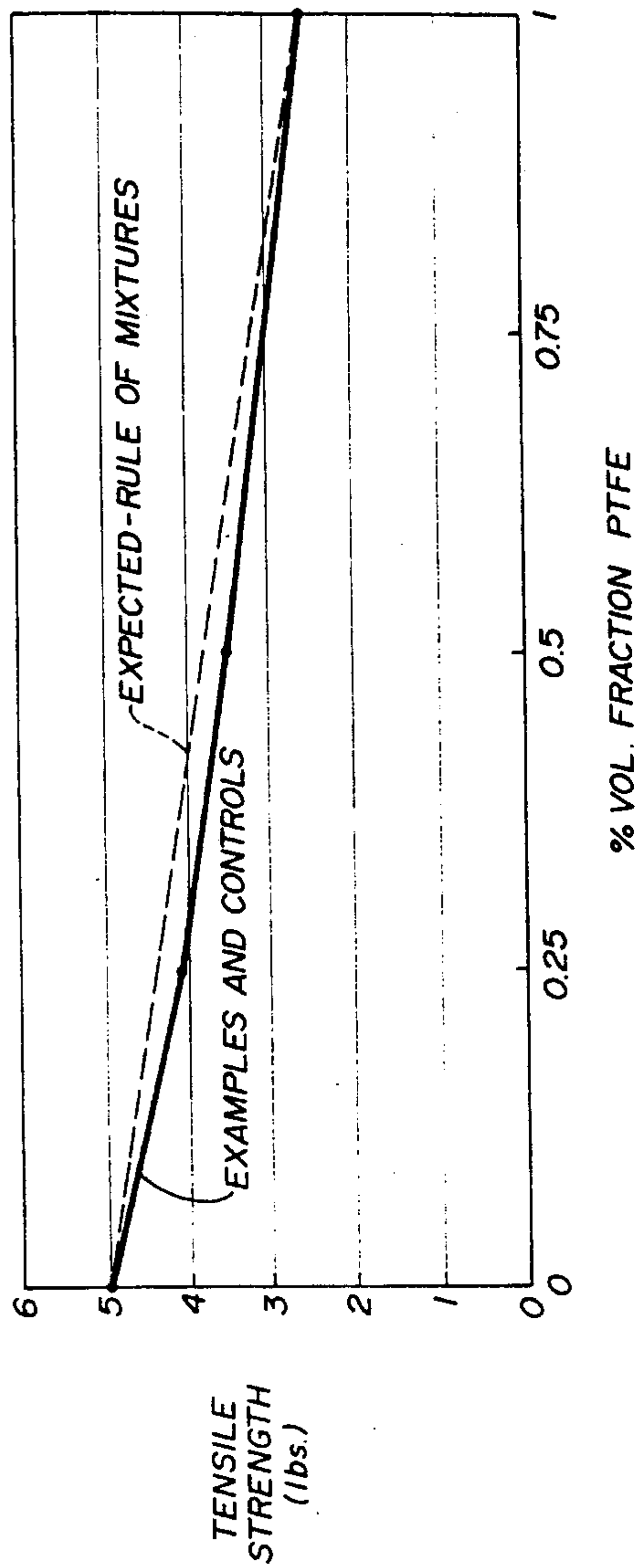
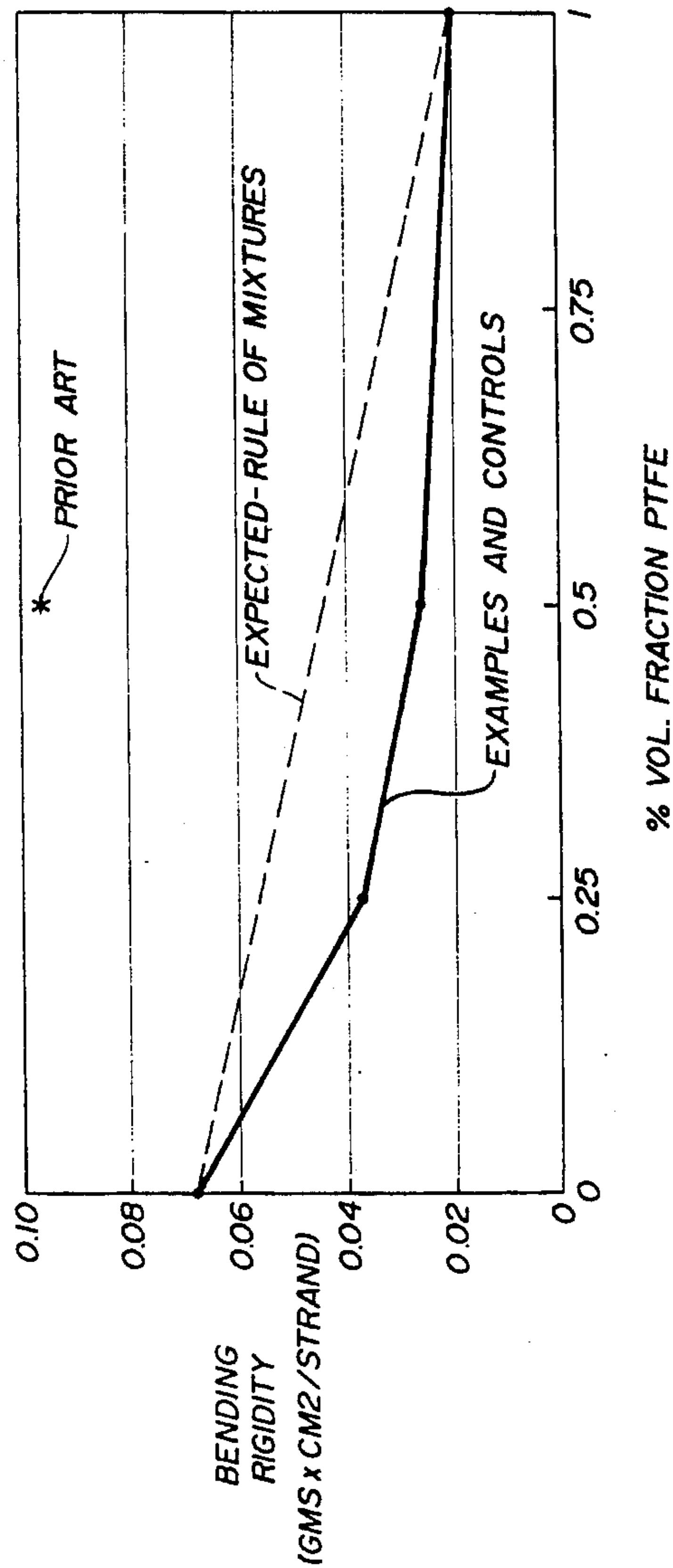

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
BENDING RIGIDITY (GMS x CM2/STRAND)
0.10
0.08
0.06
0.04
0.02
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers **22, 22'** and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)\,(P_a)+(Vf_b)\,(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

HERMES DECLARATION
EXHIBIT 5

United States Patent [19]
Silvestrini et al.

[11] **Patent Number: 4,610,688**
[45] **Date of Patent: Sep. 9, 1986**

[54] **TRIAXIALLY-BRAIDED FABRIC PROSTHESIS**

[75] Inventors: **Thomas A. Silvestrini**, East Lyme; **Joseph E. Laptewicz, Jr.**, Groton, both of Conn.

[73] Assignee: **Pfizer Hospital Products Group, Inc.**, New York, N.Y.

[21] Appl. No.: **481,612**

[22] Filed: **Apr. 4, 1983**

[51] **Int. Cl.**[4] **A61F 2/06;** A61F 2/24
[52] **U.S. Cl.** .... **623/1;** 623/2; 623/12; 128/92 C
[58] **Field of Search** .... 3/1, 1.4, 1.5; 128/92 C, 335

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Primary Examiner—Richard J. Apley
Assistant Examiner—David J. Isabella
Attorney, Agent, or Firm—Charles J. Knuth; Peter C. Richardson; Lawrence C. Akers

[57] **ABSTRACT**

A novel prosthesis for use in repairing or replacing soft tissue is disclosed, which comprises a triaxially-braided fabric element having interwoven first, second and third sets of fibers, with the fibers of the second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of the first set. An elongated ligament prosthesis exhibiting the desired properties of high strength and high elasticity may be prepared by selecting high elasticity fibers for the first set, orienting said first set of fibers in the longitudinal direction of the prosthesis and selecting fibers having high yield strength and high Young's modulus for the second and third sets. A tubular prosthesis in which high elasticity fibers are oriented in the longitudinal direction is highly suitable for use as a vascular prosthesis. A prosthesis of the invention may also be manufactured in the form of a prosthetic heart valve leaflet.

14 Claims, 6 Drawing Figures

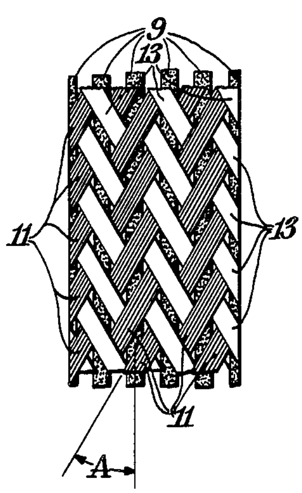


Fig.1.

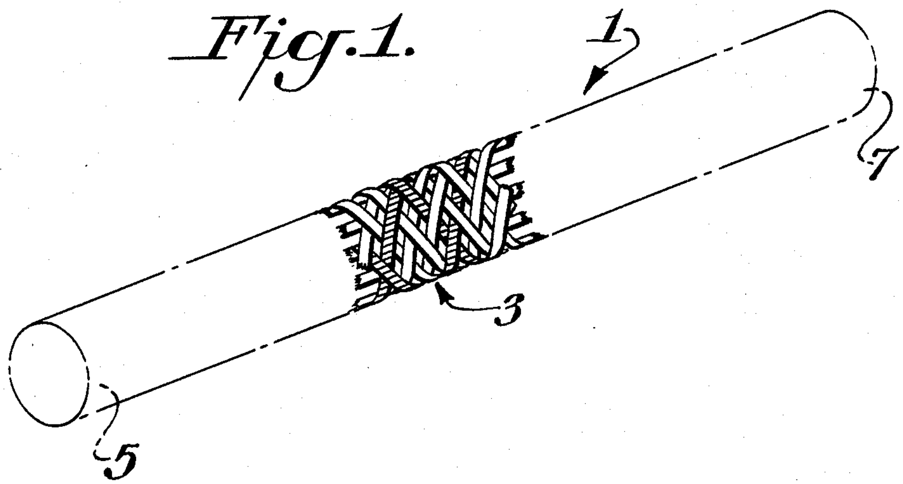
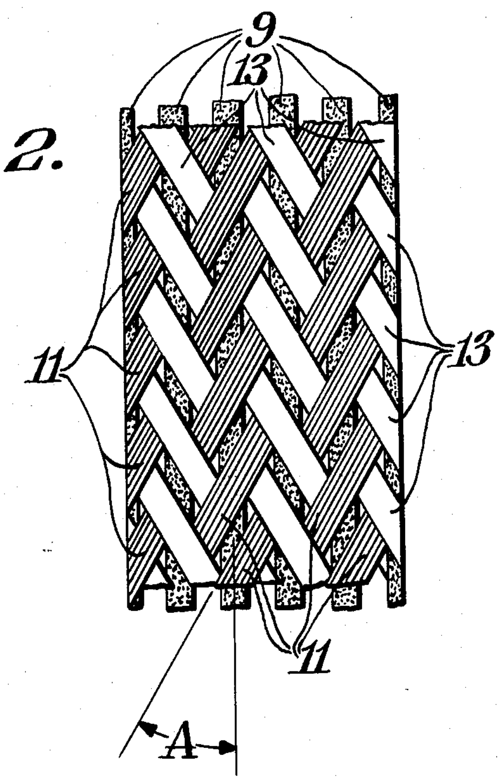


Fig.2.



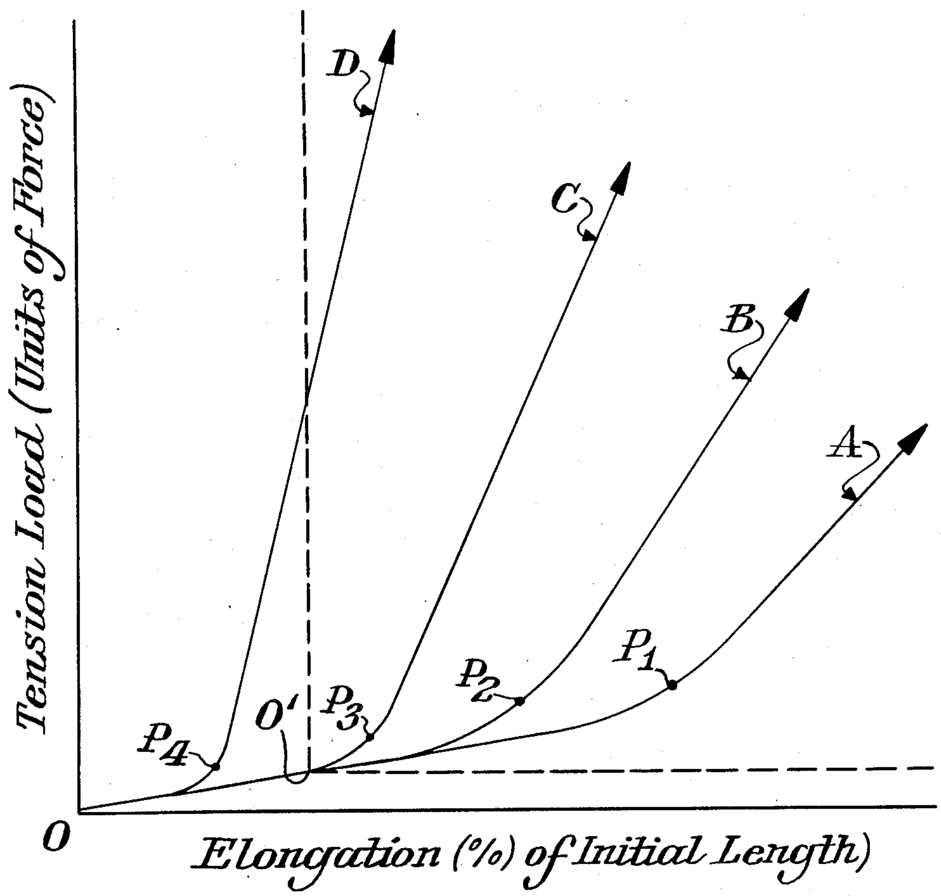

Tension Load (Units of Force)
D
C
B
A
P1
P2
P3
P4
O'
O
Elongation (%) of Initial Length)

Fig. 3.

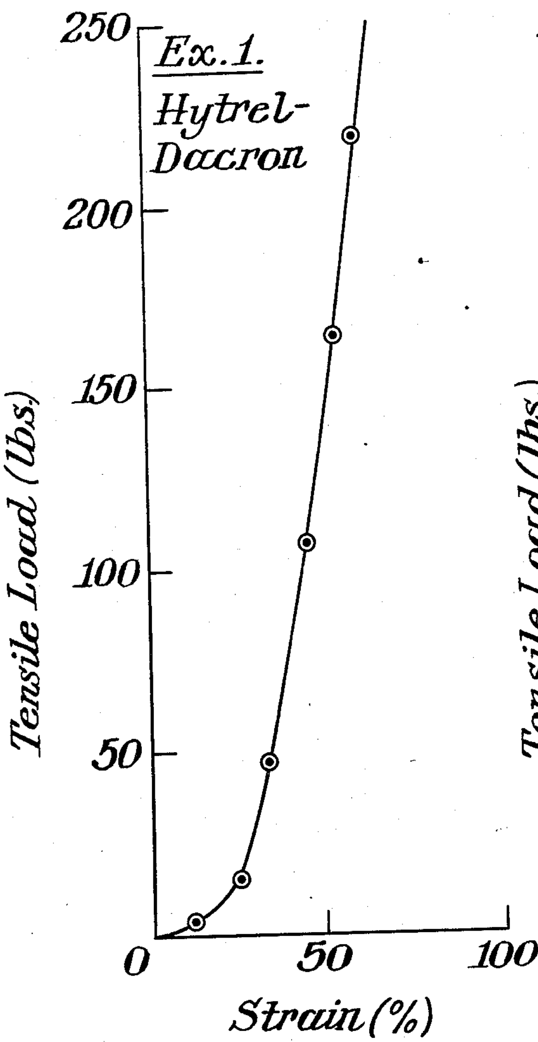

Ex. 1.
Hytrel-
Dacron
250
200
150
100
50
Tensile Load (lbs.)
0
50
100
Strain (%)

Fig. 4.

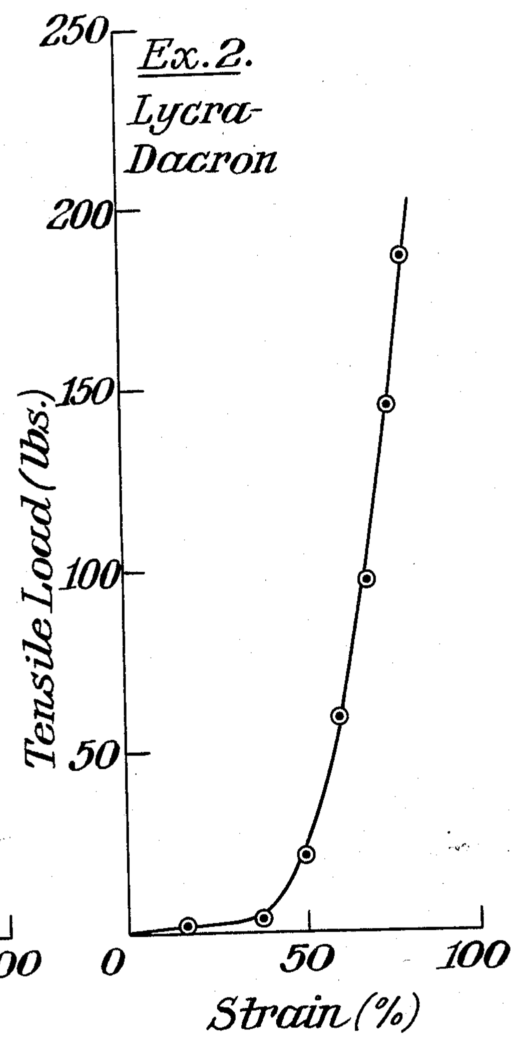

Ex. 2.
Lycra-
Dacron
250
200
150
100
50
Tensile Load (lbs.)
0
50
100
Strain (%)

Fig. 5.

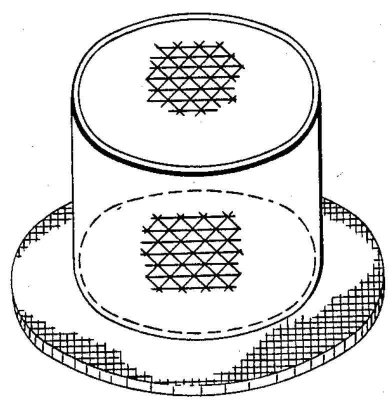


Fig. 6.

TRIAXIALLY-BRAIDED FABRIC PROSTHESIS

BACKGROUND OF THE INVENTION

The natural ligaments are elongated bundles of collagenous soft tissue that serve, among other things, to hold the component bones of joints together. The surgical treatment of diseased or damaged ligaments, e.g. the anterior cruciate ligament, has been severely hampered by the unavailability of a suitable, generally accepted ligament prosthesis. The desired characteristics for a ligament prosthesis include appropriate size and shape, biological compatibility, capability of being readily attached by the surgeon to the body of the patient, high fatigue resistance and mechanical behavior approximating that of the ligamentous tissue sought to be repaired or replaced.

The latter desired characteristic is particularly important. Natural ligaments are both strong and highly elastic, which qualities are generally not found together in a single material. Thus, for example, the anterior cruciate ligament of normal adult humans exhibits a yield point in tension of about 50 kg. at a reversible elongation of about 28%, and a break point of about 60 kg. (Typical adult human tendons are stronger and less elastic.) A number of ligament and/or tendon prostheses are known in which the load bearing body portion is fabricated essentially of a single synthetic material (see, e.g., U.S. Pat. Nos. 3,176,316; 3,613,120; 4,127,902; 4,149,277; 4,209,859; 4,255,820; 4,329,743 and 4,345,339; U.K. Pat. No. 1,602,834 and European Published Patent Appln. 51,954). These monocomponent devices generally possess insufficient longitudinal elasticity and some also exhibit inadequate longitudinal break strength. As a result of their insufficient elasticity, this type of prosthesis must be forced into the region of plastic deformation to achieve the longitudinal elongation desired for normal anatomical function, e.g. flexion of a joint, which of course permanently impairs the mechanical function of the prosthesis.

Recently, ligament prostheses have been disclosed in U.S. Pat. Nos. 4,246,660 and 4,301,551 in which the load bearing body portion is a bicomponent structure comprised of one material that imparts strength to the prosthesis and another material that imparts elasticity. The use of these prostheses alleviates the disadvantages described above for the monocomponent type of prosthesis. However, the prostheses disclosed in the '660 and '551 Patents are complex in construction and their methods of attachment to the body of the patient involve rather complicated surgical procedures.

A recent thesis (Elizabeth E. Fitzgerald, "Mechanical Behavior of Bicomponent Braids as Potential Surgical Implants", Master of Science Thesis, Cornell University, August 1979) has disclosed the use of a braided bicomponent tube as a ligament prosthesis. In this prosthesis two interwoven sets of polymeric fibers, one of a strong material and the other of an elastic material, are helically-disposed in the wall of the tube and oriented at a fixed angle with respect to one another. Each set of fibers is oriented at the same acute angle with respect to the longitudinal direction of the tube. The prosthesis may additionally comprise a monocomponent polymeric filament core.

The prosthesis disclosed in the Fitzgerald thesis has certain inherent disadvantages. First, since the fibers in the two helically-disposed interwoven sets are not idential, the prosthesis is not balanced and will tend to twist

during longitudinal elongation. Second, since the set of helically-disposed elastic fibers is angulated with respect to the longitudinal direction of the prosthesis, only a minor amount of the work performed in elongating the prosthesis longitudinally is converted to elastic energy stored in the extended set of elastic fibers. Undesirably large portions of said work are converted to elastic energy stored in the other set of strong fibers or dissipated as friction in the extending trellis-like bicomponent braided structure.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a ligament prosthesis of simple construction that exhibits a yield strength in tension and a longitudinal elasticity that are at least comparable to that of a human ligament and a resistance to longitudinal elastic deformation in tension that approximates that of a human ligament.

Is is another object of the invention to provide a balanced braided prosthesis of such construction that its longitudinal load-strain behavior can be readily "fine-tuned", while maintaining balance, to suit particular applications by changing component materials and/or braiding variables.

These and other objects of the invention are achieved with a novel prosthesis for use in repairing or replacing soft tissue comprising a triaxially-braided fabric element containing interwoven first, second and third sets of fibers, with the fibers of said first set being oriented in substantially the same direction, the fibers of said second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of the first set, and the fibers of one of said three sets having greater elasticity than the fibers of one or both of the other two of said three sets. One important embodiment of the novel prosthesis of the invention is a prosthesis adapted for use in repairing or replacing ligament or tendon tissue, in which embodiment the prosthesis has first and second opposed end portions adapted to be attached with the prosthesis in tension to the body of a patient, with said two end portions defining between them the longitudinal direction of the prosthesis, the fibers of the first set are oriented in substantially said longitudinal direction of the prosthesis the fibers of the first set have greater elasticity than the fibers of both of said second and third sets, and the fibers of the second and third sets have greater yield strength and Young's modulus than the fibers of the first set. By increasing (or decreasing) the braiding angle with other variables fixed, the resistance of this ligament or tendon prosthesis to deformation under longitudinal loading may be decreased (or increased). Preferably, the fibers of the second set in the ligament or tendon prosthesis are identical with the fibers of the third set. In a preferred design for a ligament or tendon prosthesis of the invention, the fabric element of said prosthesis has the shape of a cylindrical tube, the fibers of the first set are oriented in the longitudinal direction of said tube and the fibers of the second and third sets are helically-disposed in the wall of said tube.

The broad conception of the present invention comprises numerous other embodiments in addition to the ligament or tendon prosthesis discussed in the preceding paragraph, such as a vascular graft prosthesis in which the woven fabric element has the shape of a cylindrical tube, the fibers of the first set are oriented in the longitudinal direction of said tube, the fibers of the

second and third sets are helically-disposed in the wall of said tube, and the fibers of the first set have greater elasticity than the fibers of both of said second and third sets. The present invention also includes a prosthetic heart valve leaflet in the form of a sheet in which the fibers of the first set are oriented in the circumferential direction of the valve and have greater yield strength and Young's modulus than the fibers of the second and third sets, and the fibers of the second and third sets have greater elasticity than the fibers of the first set.

As used herein, the terms "yield strength" and "yield stress" are synonymous and refer to the tensile stress (in units of force per unit cross-sectional area) at which significant (i.e. greater than 0.2% of initial length) plastic deformation of a naturally-occurring or synthetic object occurs. The term "Young's modulus" refers to the ratio of the tensile stress placed on an object in elastic deformation to the resulting longitudinal strain. The term "elasticity" refers to the amount of recoverable elongation of a tensioned article, i.e. the percent elongation (expressed as a percentage of initial length) at the yield stress defined above. Note that as a matter of definition a "highly elastic" material (i.e. a material exhibiting a high elasticity) may be either highly resistant to elastic deformation (high Young's modulus) or not (low Young's modulus).

DETAILED DESCRIPTION OF THE INVENTION

The invention will be described in detail with reference to a preferred embodiment thereof, which is a ligament prosthesis. Reference to this embodiment does not limit the scope of the invention, which is limited only by the scope of the claims.

In the drawings:

FIG. **1** is a perspective view of a ligament or vascular prosthesis of the invention;

FIG. **2** is an enlarged view of the braided structure of the prosthesis of FIG. **1**;

FIG. **3** is a schematic representation of the load-strain behavior of the prosthesis of FIG. **1**, showing the effect of braiding angle;

FIGS. **4** and **5** depict the load-strain behavior of particular ligament prostheses of the invention, and

FIG. **6** is an exploded view of a heart valve prosthesis of the invention, in which only a portion of the braided structure of each valve leaflet is shown.

A ligament prosthesis **1** of the invention, which consists of a triaxially-braided fabric element **3** having opposed end portions **5** and **7** defining between them the longitudinal direction of the prosthesis, is shown in FIG. **1**. In the embodiment shown in FIG. **1**, prosthesis **1** and fabric element **3** are coincident, but (as will be explained below) this is not always necessarily so. Fabric element **3** in FIG. **1** has the form of a seamless cylindrical tube; although only a portion of the braided structure of fabric element **3** is shown in FIG. **1**, it is to be understood that said braided structure actually extends along the entire length of element **3** from end portion **5** to end portion **7**.

An enlarged view of the braided structure of fabric element **3** is shown in FIG. **2**, in which figure the vertical direction is the longitudinal direction of the prosthesis. Fabric element **3** contains interwoven first, second and third sets **9**, **11** and **13**, respectively, of fibers. The fibers of first set **9** are straight and oriented in substantially the same warp direction, i.e. the longitudinal direction of the prosthesis. The weft fibers of second and third sets **11** and **13** are helically-disposed in the wall of tubular fabric element **3** (see FIG. **1**) and are oriented at substantially the same acute braiding angle A (see FIG. **2**) with respect to the fibers of first set **9**. Each fiber of set **9** is held between the fibers of sets **11** and **13**. The weft fibers of sets **11** and **13** are preferably disposed in a two-up and two-down manner with respect to one another and in a one-up and one-down manner with respect to the fibers of set **9**. Other braiding patterns may alternatively be employed, such as the disposition of the fibers of sets **11** and **13** with respect to one another in a one-up and one-down or two-up and one-down manner. In FIG. **2**, braiding angle A is about 30°. Preferably, all of the fibers in fabric element **3** have circular cross-sections of about the same diameter. If desired, various fibers in one or both of the sets **11** and **13** may be dyed to provide a means to indicate the degree of tension and elongation being experienced by the prosthesis. For example, as illustrated in FIG. **1**, two fibers in each helical set may be dyed. As the prosthesis is tensioned, the spacing between the dyed fibers increases according to a predetermined relationship between tensile load and strain for the prosthesis. Thus, if implantation in a pretensioned state is desirable, the surgeon may be provided with a linear gauge showing the desired dyed fiber spacing at a desired state of pretension for the prosthesis.

Triaxially-braided fabrics such as the one depicted in FIG. **2** and the methods of manufacturing them in different configurations (flat sheets, tubes, patches, strips, etc.) are well known to those skilled in the art of manufacturing braided polymeric articles (see for example U.S. Pat. Nos. 4,191,218; 4,192,020 and 4,297,749). Braiding angles of from about 10° to about 80° are attainable. A significant advantage of using a triaxially-braided fabric element such as element **3** as a ligament prosthesis is that the element can be readily implanted in a tensioned state by attaching its two end portions, e.g. **5** and **7**, to the body of a patient (for example to the two bones making up a joint or to the two free ends of a severed natural ligament) by means of simple stapling or suturing techniques. Of course, if desired, a ligament or tendon prosthesis of the invention may include, in addition to a triaxially-braided fabric element, distinct means (for example those disclosed in U.S. Pat. No. 4,246,660) attached to the end portions of the fabric element for securing the prosthesis to the body of the patient.

In the ligament prosthesis **1** depicted in FIGS. **1** and **2** the longitudinally-oriented straight inlaid fibers of set **9** have greater elasticity than the fibers of helically-disposed sets **11** and **13**, while the fibers of sets **11** and **13** have greater yield strength and Young's modulus than the fibers of set **9**. As a result, the set **9** fibers provide the ligament prosthesis with the desired elasticity, while the set **11** and set **13** fibers provide the desired strength and resistance to longitudinal tensile deformation of the composite prosthetic article. The applied axial tensile load—% axial elongation curve for prosthesis **1** (not pretensioned) is shown schematically as curve C in FIG. **3**. Initially, the slope of the load vs. elongation curve is quite low as the load is borne primarily by the elastic fibers of set **9**. As elongation increases, however, the helically-disposed fibers of sets **11** and **13** become more aligned with the direction of elongation. As a result the slope of the load vs. elongation curve for the prosthesis increases sharply in the vicinity of point P_3.

Eventually the yield point of the prosthesis is reached, which is essentially equal to the yield point of the woven assembly of the fibers of sets **11** and **13**. An important characteristic of prosthesis **1** is the orientation of the elastic fibers of set **9** in the longitudinal direction of the prosthesis, which permits the storage of a large amount of elastic energy in the elongating fibers of this set. Significant additional elastic energy is stored in the compression of the fibers of set **9** by the fibers of sets **11** and **13** during elongation of the prosthesis. Only a small amount of applied work is dissipated as friction.

The fibers of the interwoven three sets in a prosthesis of the invention are preferably made of synthetic polymeric materials, although naturally-occurring (e.g. silk) and inorganic (e.g. stainless steel) fibers may also be used. If desired, biologically resorbable fibers may be employed. It is usually preferred that the fibers of the second and third sets be identical and equal in number. The elastic fibers of the first set in a ligament and/or tendon prosthesis of the invention such as prosthesis **1** may, for example, be selected from the group consisting of polyurethane polymers, silicone elastomers, polyester/polyether block copolymers, spandex-type polyurethane/polyether block copolymers, spandex-type polyurethane/polyester block copolymers, and hard elastic polypropylene. The strong and stiff fibers of the second and third sets in such a prosthesis may, for example, be selected from the group consisting of polyethyleneterephthalate, nylon, aromatic polyamide polymers such as Kevlar (E. I. du Pont de Nemours & Co.; Wilmington, Del.), isotactic polypropylene, polyglycolic acid and polylactic acid. Other suitable materials are readily apparent to those skilled in the art of polymer chemistry. As just one specific example, the fibers of first set **9** of prosthesis **1** may be made of a polyester/polyether block copolymer such as Hytrel (DuPont) and the fibers of sets **11** and **13** of polyethyleneterephthalate. Other alternative combinations of fibers are listed (non-exclusively) below:

Set 9	Set 11	Set 13
polyurethane polymer	nylon	nylon
polyurethane polymer	aromatic polyamide polymer	aromatic polyamide polymer
polyurethane polymer	isotactic polypropylene	isotactic polypropylene
polyurethane polymer	polyglycolic acid	polyglycolic acid
polyurethane polymer	polylactic acid	polylactic acid
polyurethane polymer	polyethyleneterephthalate	polyethyleneterephthalate
silicone elastomer	polyethyleneterephthalate	polyethyleneterephthalate
silicone elastomer	nylon	nylon
silicone elastomer	aromatic polyamide polymer	aromatic polyamide polymer
silicone elastomer	isotactic polypropylene	isotactic polypropylene
silicone elastomer	polyglycolic acid	polyglycolic acid
polyester/polyether block copolymer	polyethyleneterephthalate	nylon
polyester/polyether block copolymer	nylon	nylon
polyester/polyether block copolymer	aromatic polyamide polymer	aromatic polyamide polymer
spandex-type polyurethane/ polyether block copolymer	polyethyleneterephthalate	polyethyleneterephthalate
spandex-type polyurethane/ polyether block copolymer	nylon	nylon
spandex-type polyurethane/ polyether block copolymer	aromatic polyamide polymer	aromatic polyamide polymer
spandex-type polyurethane/ polyether block copolymer	polyglycolic acid	polyglycolic acid
spandex-type polyurethane/ polyether block copolymer	nylon	nylon
spandex-type polyurethane/ polyether block copolymer	aromatic polyamide polymer	aromatic polyamide polymer
spandex-type polyurethane/ polyether block copolymer	polyethyleneterephthalate	polyethyleneterephthalate
hard elastic polypropylene	polyethyleneterephthalate	polyethyleneterephthalate

Aside from the materials selected for the three sets of fibers in a prosthesis of the invention and the overall configuration and dimensions of the prosthesis, the resulting mechanical properties of the prosthesis, e.g. prosthesis **1** in FIGS. **1** and **2**, are also materially affected by the various braiding variables, e.g. the fiber diameters, braiding angle, braiding tension, density of windings, number ratio of fibers in the three sets and braiding pattern. Of considerable importance is the braiding angle, illustrated as angle A in FIG. **2**. As is shown schematically in FIG. **3**, the resistance of prosthesis **1** to deformation under axial loading in tension increases as the braiding angle is decreased (curve A to curve D). Furthermore, the percent elongation of prosthesis **1** (as a percentage of initial length) at which significant plastic deformation or breakage of the prosthesis commences decreases as the braiding angle is decreased. Thus it can be seen that, with all other variables fixed, the load-strain behavior of prosthesis **1** can be adjusted to approximate that of a natural ligament or tendon sought to be repaired or replaced by varying the braiding angle. Additionally, with all other variables fixed and the fibers of the second and third sets identical and equal in number, the load-strain behavior of prosthesis **1** can be substantially adjusted by varying the numerical ratio of fibers in the three sets, e.g. from 1 (longitudinal):1 (helical):1 (helical) to 0.5 (longitudinal):1 (helical):1 (helical), while maintaining a balanced prosthesis. The above-indicated change in number ratio would render the prosthesis more resistant to elongation under axial loading in tension.

In addition to mechanical properties, the wall porosity of a prosthesis of the invention may be varied in a predictable manner by altering the braiding variables, particularly the fiber diameters, braiding tension and density of windings. A relatively high porosity permits,

if desired, substantial tissue ingrowth into the wall of the fabric element of the prosthesis, while a relatively low porosity minimizes such ingrowth if it is not desired. Generally, tissue ingrowth is desired in a permanent prosthesis but not in a temporary one.

The triaxially-braided fabric element of a ligament and/or tendon prosthesis of the invention may have other shapes than the cylindrical tube shown in FIG. **1**. Thus, the fabric element may have the shape of a flattened cylindrical tube. As another example, the fabric element of a ligament and/or tendon prosthesis may have the shape of a flat elongated strip, in which the straight, longitudinally-oriented elastic fibers of the first set are disposed in essentially a single plane and each of the fibers of the second and third sets traverses said plane in a zig-zag manner (as depicted in FIG. **9** of U.S. Pat. No. 4,191,218) while maintaining a constant braiding angle.

The present invention is by no means limited to ligament and/or tendon prostheses, but includes prostheses for other soft tissue structures as well (e.g., blood vessels). Thus, for example, a vascular prosthesis of the invention such as an aortic graft prosthesis may have the same shape (but typically a different diameter) as the prosthesis **1** shown in FIG. **1**. In such a vascular prosthesis, the fibers of sets **9**, **11** and **13** are all elastic, with the straight fibers of longitudinally-oriented set **9** being more or less elastic, preferably more elastic, than the fibers of both of the other two sets. Accordingly, a tubular vascular prosthesis may be provided with high elasticity in the longitudinal direction as well as substantial elasticity in the radial direction to accomodate the pulsing flow of blood in vivo. If desired, such a tubular vascular prosthesis may include an impermeable elastic internal coating or tubular insert.

Additionally, a heart valve prosthesis of the invention (see FIG. **6**) may comprise a frame having a generally circular base defining the circumferential direction of the prosthesis and a plurality of spaced, generally parallel legs extending from the base; and a plurality of triaxially-braided fabric elements having the form of sheets and attached by conventional means to the frame in such a manner that they function as heart valve leaflets during the operation of the valve. Preferably, in each of said fabric elements, the fibers of the first set are oriented in the circumferential direction of the valve when the valve is in the open position, the fibers of the second and third sets traverse the first set of fibers in a zig-zag manner (as depicted in FIG. **9** of U.S. Pat. No. 4,191,218), the fibers of the first set have greater yield strength and Young's modulus than the fibers of the second and third sets, and the fibers of the second and third sets have greater elasticity than the fibers of the first set. Accordingly, an artificial heart valve prosthesis leaflet is provided that is capable of substantial elastic stretching in directions generally orthogonal to the circular base of the frame of the heart valve prosthesis.

The use of prostheses of the invention to repair or replace soft tissue requires only simple surgical procedures. After diseased or damaged soft tissue has been removed, the ends of a prosthesis of the invention may be readily attached to bone (e.g. with conventional bone staples) or to soft tissue (e.g. by suturing). Prostheses of the present invention may be cut to a desired length without unravelling. If desired, two tubular prostheses of the invention may be readily anastomosed in an end-to-end fashion. To prevent fraying of the triaxially-braided fabric element the free ends of the fibers at the edge of the element may be fused together, e.g. by ultrasonic welding or by dipping the edge of the element in a suitable coating material. A ligament and/or tendon prosthesis of the invention may be preconditioned before use by applying and releasing an axial tensile load (e.g. 60 lbs.) a number of times. In the case of an anterior cruciate ligament prosthesis, the prosthesis is preferably implanted in a longitudinally pretensioned state. Then, the observed load-strain behavior of the implanted prosthesis is that relative to an origin such as the origin O′ on curve C defined by the dotted abscissa and ordinate in FIG. **3**.

Conventional techniques (see for example the article by James, S. L., "Biomechanics of Knee Ligament Reconstruction", Clin. Orthoped. and Related Res., No. 146, pp. 90–101 (Jan.-Feb. 1980)) may be employed in attaching a ligament prosthesis of the invention to the patient's body. Preferably, a short end length of the prosthesis (e.g. prosthesis **1**) is folded over once (i.e. lap folded) and the attachment to the body effected at this doubled region. The surgical joining of a severed natural tendon may be facilitated by slipping a tubular prosthesis of the invention over the free end of one portion of the severed tendon, surgically joining the two portions of the tendon and then attaching the prosthesis to the two respective portions of the severed tendon. The prosthesis serves to support the healing tendon and can be removed after the healing has been accomplished.

By appropriate selection of braiding and other variables the mechanical properties of various natural human ligaments and tendons can be closely approximated by a prosthesis of the present invention. Often, in order to make such a match, it is desired that the prosthesis exhibit a tensile break point of at least about 75 kg. and, after initial pretension, an overall load modulus of from about 200 kg./(unit of strain based on pretensioned length) to about 600 kg./(unit of strain based on pretensioned length) over a range of substantially recoverable tensile elongation beginning at the pretensioned state and extending over a strain equal to at least about 25 percent of the initial pretensioned length of the prosthesis. Two examples of prosthesis **1** having these desired properties are set forth below. These examples are not to be construed as limiting the invention.

EXAMPLE 1

Set 9—Longitudinal fibers—48 ends—Hytrel Type 5556 polyester/polyether block copolymer monofilament (E. I. du Pont de Nemours & Co.; Wilmington, Del.)—220 denier

Set 11—Helical fibers—46 ends of 220 denier Dacron Type 52 polyethyleneterephthalate twisted multifilament (Du Pont) and 2 ends of 250 denier Dacron Type 55 polyethyleneterephthalate twisted multifilament (Du Pont) dyed with D & C green dye No. 6

Set 13—Helical fibers—same as set 11 Prosthesis configuration—flattened circular cylindrical tube 1.5 inches in length—21 mm. circumference

Braiding angle—45°

Braiding pattern of sets 11 and 13 with respect to one another—2-up and 2-down

Density of windings of sets 11 and 13 -35 picks per inch

Braiding tension—50 to 55 g. on longitudinal fibers, 3 oz. braider carrier springs on helical fibers

The above-described prosthesis exhibited the load-strain behavior shown in FIG. **4** (the origin is drawn with reference to the untensioned state). The prosthesis exhibits a tensile break point of 250 lbs. = 113 kg. If the

prosthesis is pretensioned to, for example, 10 lbs. tension (20% strain), it will exhibit an overall load modulus over a range of 37% of the pretensioned length of the prosthesis (equivalent to 44% of untensioned length) of (250-10) lbs./(0.37 unit of strain)=295 kg./(unit of strain). Above 20 lbs. load, the prosthesis will exhibit a substantially constant load modulus of (250-20)lbs./(0.31 unit of strain)=340 kg./(unit of strain). No distinct yield point is observed to breakage.

EXAMPLE 2

Set 9—Longitudinal fibers—48 ends—Lycra Type 127 spandex-type polyurethane/polyether block copolymer coalesced multifilament (du Pont) —280 denier
Sets 11 and 13—Helical fibers—same as in Example 1
Prosthesis configuration—same as in Example 1 except that circumference of tube is 19 mm.
Braiding angle—48°
Braiding pattern of sets 11 and 13 with respect to one another—2-up and 2-down
Density of windings of sets 11 and 13 -42 picks per inch
Braiding tension—20 to 25 g. on longitudinal fibers, 3 oz. braider carrier springs on helical fibers

The above-described prosthesis exhibited the load-strain behavior shown in FIG. 5 (the origin is drawn with reference to the untensioned state). The prosthesis exhibits a tensile break point of 202 lbs.=92 kg. If the prosthesis is pretensioned to, for example, 7 lbs. tension (40% strain), it will exhibit an overall load modulus over a range of 29% of the pretensioned length of the prosthesis (equivalent to 40% of untensioned length) of (202-7) lbs./(0.29 unit of strain)=305 kg./(unit of strain). Above 20 lbs. load the prosthesis will exhibit a substantially constant load modulus of (202-20) lbs./(0.23 unit of strain)=360 kg./(unit of strain). No distinct yield point is observed prior to breakage.

We claim:

1. A prosthesis for use in repairing or replacing ligament or tendon tissue, said prosthesis having first and second opposed end portions adapted to be attached with the prosthesis in tension to the body of a patient, with said two end portions defining between them the longitudinal direction of the prosthesis, and said prosthesis comprising a triaxially-braided fabric element containing interwoven first, second and third sets of fibers, with the fibers of said first set being elastic and oriented in substantially said longitudinal direction of the prosthesis, the fibers of said second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of said first set, the fibers of said first set having greater elasticity than the fibers of both of said second and third sets, the fibers of said second and third sets having greater yield strength and Young's modulus than the fibers of said first set, and said prosthesis exhibiting a tensile break point of at least about 75 kg.

2. A prosthesis of claim **1** wherein said braiding angle is from about 10° to about 80°, whereby the resistance of said prosthesis to longitudinal deformation under longitudinal tensile loading decreases as said braiding angle is increased.

3. A prosthesis of claim **2** wherein the fibers of said second set are identical with the fibers of said third set.

4. A prosthesis of claim **3** wherein the fibers of said first set are made of a polyester/polyether block copolymer and the fibers of said second and third sets are made of polyethyleneterephthalate.

5. A prosthesis of claim **3** wherein the fibers of said first set are made of a polyurethane/polyether block copolymer and the fibers of said second and third sets are made of polyethyleneterephthalate.

6. A prosthesis of claim **3** wherein the fibers of said first set are made of a polyurethane/polyester block copolymer and the fibers of said second and third sets are made of polyethyleneterephthalate.

7. A prosthesis of claim **1** wherein said element has the shape of a cylindrical tube, the fibers of said first set are oriented in the longitudinal direction of said tube and the fibers of said second and third sets are helically-disposed in the wall of said tube.

8. A prosthesis of claim **1** wherein said element has the shape of a flat elongated strip, the fibers of said first set are oriented in the longitudinal direction of said strip in essentially a single plane and the fibers of said second and third sets traverse said plane in a zig-zag manner.

9. A prosthesis of claim **1** wherein said fabric element includes means to visually indicate the degree of extension of said prosthesis in tension.

10. A prosthesis of claim **3** wherein said triaxially-braided fabric element contains interwoven first, second and third sets of synthetic polymeric fibers, and said prosthesis exhibits, after initial pretension, an overall load modulus of from about 200 kg./unit of strain) to about 600 kg./(unit of strain) over a range of substantially recoverable tensile elongation amounting to at least about 25 percent of the initial pretensioned length of the prosthesis.

11. A vascular prosthesis comprising a triaxially-braided fabric element containing interwoven first, second and third sets of fibers, with said element having the shape of a cylindrical tube, the fibers of said first set being elastic and oriented in the longitudinal direction of said tube, the fibers of said second and third sets being elastic and helically-disposed in the wall of said tube at substantially the same acute braiding angle with respect to the fibers of said first set, and the fibers of said first set having greater elasticity than the fibers of both of said second and third sets.

12. A prosthesis of claim **11** wherein said braiding angle is from about 10° to about 80°.

13. A heart valve prosthesis comprising:

a frame having a generally circular base defining the circumferential direction of the prosthesis and a plurality of spaced, generally parallel legs extending from said base; and

a plurality of triaxially-braided fabric elements having the form of sheets and attached to said frame in such a manner that they function as heart valve leaflets during the operation of the valve, with each of said fabric elements containing interwoven first, second and third sets of fibers, with the fibers of said first set being oriented in substantially the same direction and the fibers of said second and third sets being oriented at substantially the same acute braiding angle with respect to the fibers of said first set, and wherein, in each of said fabric elements, the fibers of said first set are oriented in the circumferential direction of said valve when said valve is in the open position, the fibers of said second and third sets traverse said first set of fibers in a zig-zag manner, the fibers of said first set have greater yield strength and Young's modulus than the fibers of both of said second and third sets, and the fibers of said second and third sets have greater elasticity than the fibers of said first set.

14. A prosthesis of claim **13** wherein said braiding angle is from about 10° to about 80°.

* * * * *

HERMES DECLARATION
EXHIBIT 6

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

TRAVEL TRANSCRIPT

DePUY MITEK, INC.,)
Plaintiffs,)
)
vs.)
)
ARTHREX, INC., a Delaware)
corporation,)
Defendants.)
)

DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Courtyard Marriott, 423 Speen Street, Natick, Massachusetts, on Thursday, 26 January, 2006, commencing at 10:44 a.m.

in college. My next professional assignment --
Q. Generally when you were at Gentex, what kind of -- what kind of work were you doing?
A. Right. Product development, using high-tenacity fibers, aromids, polyethylenes, that type of --
Q. Okay.
A. Okay. Then I moved to -- after -- after MIT, I took a position as a senior scientist at Chemfab in Merrimack, New Hampshire, where I also worked on protective clothing and fluoropolymer composites.
Q. What are fluoropolymers?
A. Fluoropolymers are a generic class of polymers that contain fluorine that include PFE, FEP, PFA, high -- high-performance plastics, many of which are made by Dupont.
Q. Okay. And what was the name of that company?
A. Chemfab, C-h-e-m-f-a-b.
Q. And when did you work for them?
A. To the best of my recollection, I started in 1984 and finished in 1987.
Q. And what kind of products were you working on there?

A. I was working on protective clothing -- chemical protective clothing and on architectural materials.
Q. What do you mean by that?
A. One of Chemfab's businesses is the fluoropolymer membrane that's used on the large sports stadiums, such as the Metro dome or the Carrier Dome.
Q. Part of the roof?
A. It is the roof.
Q. Okay.
A. It's an interesting technology. It's an interesting fluoropolymer reinforced technology.
Q. And what was your responsibilities? You said you were a senior engineer. What did you do?
A. Yeah. Again, it was product development, and it was small company environment, so responsibilities were designing the products, executing prototyping, transferring into manufacturing.
Q. I take it that neither of these jobs involved any products in the medical field?
A. Correct.
Q. Okay. What came next?
A. After Chemfab came an assignment with

Ciba-Geige in Anaheim, California. That was in the field -- also in the field of high-performance composites, nonmedical; again, very high-strength fibers, reinforced, most -- plastics, mostly for aerospace applications.
Q. What kind of high-strength fibers were you working with then?
A. Primarily carbon fibers and aramid.
Q. You've used the term aramid a couple of times today. What are aramids?
A. Aramids are aromatic nylons, and they are high-strength nylons used typically for either body armor or very high-strength plastics.
Q. Are there some names of some products?
A. Yes. The most common one is Kevlar. It's a Dupont trade name. K-e-v-l-a-r.
MR. SABER: Off the record.
(Discussion off the record.)
Q. Okay. So -- and what was your -- what was your role at Ciba-Geige?
A. Ciba-Geige, I was actually in market development, and it involved working with the major aerospace equipment suppliers in terms of finding new markets for these materials and their products.
Q. So, you actually weren't developing the

products?
A. I was less developing products. I was more working with customers, trying to marry the technology to their needs.
Q. Why were you working in the marketing field at that point or marketing --
A. Yeah. No, it was some -- it was an interest I had, and it was still very technical marketing.
Q. All right.
A. But I thought at that point I wanted to be a marketing person.
Q. All right. I take it from the next thing you're going to tell me you went back to being more technical?
A. Yeah, it was fun.
Q. What came next?
A. Next came --
Q. How long were you at Ciba-Geige?
A. Just one year.
Q. That -- so that was about '80 --
A. '88.
Q. '87, '88?
A. Yes. '88 I joined Johnson & Johnson at their Ethicon division, suture division in

Somerville, New Jersey; and my responsibilities were in suture research and specifically on braided suture product development.

Q. When in 1988 did you begin at Johnson & Johnson, or Ethicon --

A. Yeah.

Q. -- to be more precise?

A. Let me just -- oh, I know. February 29th of 1980. It happened to be a leap year, so I only had an anniversary every four years.

Q. Every now and then you get something like that that helps.

A. Right.

Q. And how long were you at Ethicon -- was that the first time that you had worked with -- in the medical field?

A. Yeah, that was my first formal medical device job.

Q. And I would assume it's obviously the first time that you worked with sutures.

A. Yes.

Q. Is it the first time you had worked with braided materials?

A. No. I had used braids extensively in Ciba-Geige and less so at -- but some -- at Gentex,

and prior to that I had published some papers with my undergraduate professor in the field of three-dimensional braids as an undergraduate.

Q. Let me -- let me go back and ask you about some of your professional writings, if I may. Have you -- how often -- have you been published?

A. Yes.

Q. And how often?

A. Maybe five, six articles spread between peer-review journals, trade journals, proceedings of technical meetings.

Q. Could you tell me about what you can talk -- as many of the articles that you can tell me about -- it's not that many -- so what their subjects were.

A. Right. So, dating back to -- the early articles were -- there was one on a technology called triaxial woven materials. That was back as an undergraduate, and one on three-dimensional braids --

Q. Before we go forward --

A. Please. Sure.

Q. -- on those, let me just get a little more detail on that. A triaxial woven material, what is that?

A. Yeah, that is -- most conventional welding materials have two sets of yarns that interlace at a 90 degree angle. The triaxial wovens had three sets of yarns that essentially interlace at 120 or 60 degrees, depending which angle you want to take, but three sets of yarns.

Q. And was this for clothing?

A. This was actually for inflated structures, inflatable --

Q. What does that mean?

A. Such as architectural -- air-supported architectural stadiums, tennis courts inflatables like, you know, military dirigibles and blimps, those type of products.

Q. None of that involve -- those were not braided materials?

A. Those were not braided.

Q. And none of those were in the medical field?

A. None of those were in the medical field.

Q. Okay. The second one that you said was three-dimensional braids?

A. Right.

Q. And what do you mean by that?

A. These are a nonconventional braiding

technology in that most braids are tubular. You have two sets of yarns interlaced so that you have essentially a cylindrical structure, and they can be filled with a -- core yarns. The three-dimensional braids involve a structure where -- essentially, a solid braid. So, you have multiple carriers that are -- are moving from the core into the sheathe and back, so it's -- it's totally interwoven together.

Q. Interwoven. You're talking about the sheathe and the core?

A. Right. All the filaments. There's no really distinct sheathe and core at that point. It's just one solid braid.

And we were -- the professor that I worked with on this was looking at these for high-performance military composites through medical devices, such as anterior cruciate ligament replace and things like that.

Q. When did you do this paper?

A. This was a paper -- 1982.

Q. And was that as part of your schooling?

A. It was -- it was research related to my schooling.

Q. Right. And which -- which -- where were

Page 18

you at this point?
A. I was still at Philadelphia College.
Q. This is while you were an undergraduate?
A. Yes.
Q. And was there a paper published as a result of this work?
A. There was a paper published in the Journal of Industrial Fabrics.
Q. And that's under your professor's name as well as yours?
A. Yes.
Q. And what was the professor?
A. Frank Ko, K-o.
Q. And do you know when -- that was in 1982, did you tell me?
A. Yes.
Q. Okay. Let's go on to some of the other papers.
A. Okay. Yeah. And I'm not clear on the order of these, but there was a paper on corrosion resistance of 3/16ths stainless steel after work hardening. I don't believe that would be very relevant for this discussion.
Q. Well, what is corrosion resistance?
A. It relates to its ability to not rust in

Page 19

the body and after it's been mechanically deformed.
Q. And when did you work on this paper?
A. This was approximately 1994.
Q. And what were the circumstances surrounding this paper?
A. This was relating to surgical staples, and I was at the time at Ethicon Endosurgery, which is medical device supplier. It's part of the Johnson & Johnson family. And the research was around our stapling products and actually corrosion and MRI compatibility.
Q. This paper had nothing to do with sutures, I assume?
A. Nothing.
Q. And nothing had to do with braided materials.
A. Nothing.
Q. Okay. Why don't you tell me about the next one that you can recall.
A. Okay. By the way, none of the following ones will have anything to do with braids.
Q. Okay. And will any of them have anything to do with sutures?
A. Or sutures.
Q. Right.

Page 20

A. So, I mean, there's one on injection molding of polycarbonate. That was part of an MDDI meeting in New York -- Medical Device and Diagnostics Industry.
Q. The injection molding one was when?
A. That one was 19 -- give me one minute here -- 1992 to '96. That was either '95 or '96.
Q. And what journal was it published in?
A. That was in the proceedings of the MDDI meeting.
Q. And the one on the corrosion resistance, what was that published in?
A. Yeah. That's published in one of the biomedical journals, but I don't have the reference in front of me.
Q. Okay. What other -- what other articles --
A. Yes. There was an article -- well, it was actually a presentation was published. It was more of a presentation than an article, but --
Q. Okay.
A. That was last year at the University of Washington -- yeah.
Q. And what was the subject?
A. Well, the subject is next generation

Page 21

drug-eluting stents.
Q. Stents?
A. Stents, yeah. I'm trying to think of the name of the Washington consortium -- the name of the meeting. But it was at University of Washington Seattle. It was in February of 2005.
Q. And are there any other ones?
A. No.
Q. On that note, let me ask you a bit about patents. Are you a named inventor on any patents?
A. Yes.
Q. How many?
A. I believe currently it's either nine or ten.
Q. Okay. How many of those -- let's start with patents that are in the field of sutures. How many are there in sutures? We're obviously going to be talking about the 446 patent today. I assume that's one of them.
A. Right. Yeah. I'm just going through my -- my list of patents. That -- to my recollection, that's the only one I can think of that's a direct suture patent. To be honest with you, I haven't looked at my list for a while.
Q. Sure.

A. But I'm pretty sure that's the case.
Q. Do any of the other patents involve braided materials?
A. I'm trying to remember on my Mitek patents which involve suture anchors. If they are, it's related to the -- there may be some patents relating to an anchor with a suture, but to the best of my recollection, that is the only one that's directly on sutures.
Q. The ones on suture anchors, which I understand, of course, can have a suture, were any of the inventive steps having anything to do with the suture or just the anchor part?
A. No, the inventive steps were anchor related.
Q. Suture was just a piece of the --
A. Part of the deal, yeah.
Q. What patents do you have on suture anchors?
A. There's an umbrella anchor patent, which is the main one.
Q. Do you have any sutures that deal with high-performance fibers?
MR. BONELLA: Object to form.
Q. The patents -- I'm sorry. Let me restate

that. Do you have any patents that deal with high-performance fibers?
MR. BONELLA: Object to form.
A. Do I have any patents? Well, other -- the one that we're speaking of I think -- I believe includes high-performance fibers. Beyond that, I'm sorry. I -- I can't recollect my full list of patents right now.
Q. Okay. And do any of your patents deal with coating -- putting coatings on materials?
A. Yes.
Q. Which ones?
A. There's one that involves a lubricious coating on a medical device. This patent sutures with -- that includes coatings, and so, I can think of at least two.
Q. We'll, of course, talk about the 446 patent in much more detail today.
A. Sure. Yeah.
Q. But tell me about this other patent which involved a lubricious coating on a medical device.
A. Right. It was -- it is a patent for a device which is an ancillary device for doing laparoscopics surgery; and it involves a lubricious coating on an -- essentially an abdominal lift

device which, rather than the conventional procedure, involves insufflating the abdomen to get space to do the endoscopic surgery for, for example, gallbladder removal; and this invention is a -- is a device that goes through a hole in the abdomen, mechanically lifts the abdominal wall, and the lubricious coating allows for easy insertion and egress of the device.
Q. What do you mean by "easy insertion and egress of the device"?
A. Lower force to the surgeon and less trauma through the coating lubricity.
Q. Less force means that it would slide in and slide out easier?
A. Yes.
Q. And less trauma to the patient means what?
A. Less trauma to the patient would mean two things: There is a trauma at the insertion site related to just the friction of the device against the tissue, if you will; also, if it's difficult to insert the device, you run the risk of the device causing blunt trauma to the organs underneath. So, it's kind of a more controlled insertion if -- if the force is lowered.
Q. Do you recall the number of this patent?

A. No.
Q. And do you know when you -- when it was issued to you?
A. It was part of my work at Ethicon Endosurgery, which was from 1992 to '96.
Q. So, the -- at least the work was done then?
A. Yes.
Q. But you don't know when the patent issued?
A. And the patent issued -- '96. It was no later than '97.
Q. Okay. Are your other -- are there any other patents that deal with coatings, or those are the only two that you can recall?
A. Those are the only two I can recall at this moment.
Q. Okay. Do any of your patents deal with the medical field generally -- devices in the medical field or methods in the medical field, or do all of them?
A. Yeah, all of them, except one for a chemical protective clothing.
Q. And that's something you did early --
A. That was back in Chemfab.
Q. Were you a named inventor in any patent

applications which did not become patents?
A. Clarification? That would mean -- how far along the process --
Q. Well, let me break that into two parts. Let's say where you were a named inventor and no patent issued and the file is now dead; you know, it's not going to issue as a patent.
MR. BONELLA: I think you mean the patent's been applied for.
MR. SABER: That's right.
Q. It was applied for but it didn't go through, and it's been abandoned since.
A. I don't believe so.
Q. Okay. And are there -- anywhere you are named as an inventor, they applied for a patent, but it's still pending?
A. Yes.
Q. Okay. In that group, are there any that have to do with sutures --
MR. BONELLA: Just caution you, if that's information -- if there's information in these patents that's -- could be secret information, either it may or may not be, if it's still pending before the patent office, then it might be confidential information to Boston Scientific or

one of the other employers, so to the extent you can answer his question without revealing confidential information, you know, you should feel free to do so. But otherwise, I suspect you probably had a confidentiality agreement with Boston Scientific --
THE WITNESS: Sure.
MR. BONELLA: -- that you may be bound. I just don't know the facts. You may or may not -- whether it's public or not, but to the extent you can answer his question generally without revealing any confidential information --
THE WITNESS: I think I can answer it generally.
Q. I'm not trying to get into confidential -- at least by these generalized questions. That's why I tried to ask the question in a pretty general way. We'll see if I need to ask anything more specific but --
A. All right. I think -- I believe that the pending patents' applications are not in the field of sutures. They are in the field of my most recent --
Q. Can you tell me generally what field they're in?

A. Medical. Stents -- stent and drug delivery technology.
Q. Do any of those -- do you have patents on stents as well?
A. No patents issued on stents.
Q. Okay. Going back then to the ones that are -- the pending applications, do any of them involve coating issues?
MR. BONELLA: Object to the form.
A. That actually is getting close to the confidential side of -- I mean, I can say generically, yes, they are involved with coatings on stents.
Q. Uh-huh. How many pending applications are there?
A. I'm aware of at least two.
Q. Do either of these pending applications have to do with fibers?
A. No.
Q. Do any of these applications have to do with braiding?
A. No.
Q. Going back to the existing patents -- the nine to ten -- do any of those have to do with braiding technology in any way, other than the --

the 446 patent we're speaking about here today?
A. No, I do not believe so.
Q. Let's go back to your -- your work history. We were -- I believe you told me you were at Ethicon starting February 29th, 1988, and you were in suture research. And how long were you in that position?
A. For the vast majority of the four years I was at Ethicon, I was in the suture research area.
Q. So, it was 1988 to 19 --
A. '92.
Q. -- 92. Did all of that work have to do with braided sutures?
A. Most of the work had to do with braided sutures.
Q. And what position did you have during that period of time?
A. I was senior scientist, and then I was promoted to section manager.
Q. Of what section?
A. It was just section manager, suture research.
Q. And when you were a section manager, what -- what suture research were you managing?
A. Right. It was primarily braided sutures,

Page 38

oh, why did you leave Mitek to go to Boston Scientific?
A. I was recruited by someone that I had worked with in the past, and I was interested in the drug-eluting technology.
Q. And where is -- but where were you working when you were at Boston Scientific?
A. Natick, Massachusetts.
Q. Where we are now?
A. Yeah. It's a stone's throw away.
Q. And I think you told me you recently switched jobs?
A. Yes.
Q. Who are you working for now?
A. I am with a start-up company named Cappella, C-a-p-p-e-l-l-a, and I'm the vice president of research & development.
Q. And why did you switch from Boston Scientific to Cappella?
A. Desire to go to a small company and additional responsibility.
Q. And what field are they in?
A. They are in drug-eluting stents for bifurcation disease.
Q. So, it's a somewhat similar field to

Page 39

where --
A. It's very similar to.
Q. -- to where Boston Scientific was.
A. Yeah.
Q. And when did you start with Cappella exactly?
A. The -- January 9th.
Q. Okay. What did you do to prepare for your deposition today?
A. I reviewed the Hunter patent.
Q. Anything else?
A. No.
Q. Did you review any other documents --
MR. BONELLA: Anything that we reviewed together or things that I showed you, he's not entitled to know.
THE WITNESS: Right.
MR. BONELLA: That's attorney/client privileged work product, so you're not entitled to that. If you reviewed other documents, other things that I showed you, you should answer that, but to the extent or things I showed you we discussed, that's privileged, and he's not entitled to know that, so I'm instructing you not to answer to that extent, but outside of that, you can

Page 40

answer.
MR. SABER: Well, I think I'm entitled to an answer whether he reviewed all the documents. When it gets into the specifics of it --
MR. BONELLA: Sure.
MR. SABER: -- I may disagree with you, but that's a different question.
MR. BONELLA: So, did you review other documents? Why don't we answer that question yes or no for now. The question is, did you review other documents? Just answer that yes or no.
A. Yes.
Q. Other than any preparation you did together with counsel, did you review any documents other than the Hunter patent?
A. No. No.
Q. Excuse me?
A. No.
Q. But there were documents that you reviewed with counsel.
A. Yes.
Q. And when did that occur?
A. That occurred yesterday and briefly last fall.
Q. Were those, as best as you recall, the

Page 41

same documents that you reviewed on those two occasions or were they different documents?
A. Same documents.
Q. Did you review with counsel lab notebook material?
MR. BONELLA: I'll object and instruct you not to answer that question.
Q. Will you follow your counsel's advice?
A. Yes.
Q. Can you describe to me generally the kinds of documents that you reviewed?
MR. BONELLA: I object and instruct you not to answer that question.
A. I accept my counsel's advice.
Q. Okay. How long did you meet with -- you met with counsel yesterday in preparation for this deposition.
A. Yes.
Q. And how long did you meet, approximately?
A. Four hours.
Q. For purposes of this deposition, have you met with counsel any time other than yesterday?
A. No.
Q. Did you have -- have you spoken with counsel over the phone in preparation of this -- in

preparation for this deposition?
A. Only to arrange a meeting time.
Q. Nothing substantive.
A. Just logistics, right.
Q. Nothing substantive. Other than for purposes of preparing for this deposition, have you -- have you done anything -- have you had any role at all with respect to your work that led to the Hunter patent or anything else involving this litigation?
MR. BONELLA: Object to the form of the question.
Q. Let me rephrase that question. Have you -- have you been contacted -- have you met with counsel for any other purpose in connection with this litigation --
MR. BONELLA: Object to the form.
A. I --
Q. -- other than to prepare for today?
A. Right. No. Again, we met briefly last year, just met with counsel --
MR. BONELLA: I instruct you not to answer to -- don't disclose any communications that we had, any substance of our discussion. You tell him who, what, when, where, but not what we discussed.

A. Sure. It was just that --
Q. Yeah. I was trying to ask a general question to just follow up. You've met with counsel previously in, say, the last year?
A. Yes.
Q. Okay. How many times in the last -- let's say the last two years -- have you met with J&J's counsel other than yesterday?
A. Once.
Q. Okay. When was that meeting?
A. That was a meeting that I referred to last fall.
Q. In a general sense, what was the purpose of that meeting?
MR. BONELLA: Object to the form.
Q. And again, I'm not asking you to disclose what you actually discussed at that meeting.
MR. BONELLA: Instruct you not to answer to the extent -- I mean, he's not entitled to know why we met.
A. I accept my counsel's --
MR. SABER: I think I am --
MR. BONELLA: Well, it depends how he's going to answer.
MR. SABER: Yeah. I know. That's why I'm

trying to say -- I'm just trying to get the same answer I would get if this were a document on the privilege log. That's all I'm trying to do so I understand the general subject matter of the meeting.
MR. BONELLA: If you want to take a break, I will talk with him so he can answer it the way you want to answer it, but I don't want him to answer the way he --
MR. SABER: Let me just try.
MR. BONELLA: If you want to take a break, I'll tell him, you know, where the contours are.
MR. SABER: Let me just try and see if you may need a consultation.
Q. Can you tell me the general subject matter of the meeting with -- that you had with counsel? And I'm not trying to get the specific communications.
MR. BONELLA: And I want to take a break and consult the witness.
MR. SABER: Go ahead. You can.
(Recess was taken.)
(Question read back.)
A. Michael described to me that there was a case on the Hunter patent. That was the general

purpose.
Q. Well, why was he meeting with you?
A. Oh, as --
MR. BONELLA: Object to the form.
Q. Do you have an understanding why?
MR. BONELLA: If you want to know the general subject matter of the meeting --
MR. SABER: Yeah.
MR. BONELLA: -- that's different than what you're asking. You're asking why. That's implying that you are -- that a legal theory --
Q. What was the general subject matter that you and Mr. Bonella discussed?
MR. BONELLA: Okay. You can answer that generally -- general subject matter, but nothing specific about communications, what we looked at, any documents we looked at, any communications that we had, just the center subject matter.
A. The general subject matter was this pending case between Arthrex and Johnson & Johnson.
Q. Okay.
A. And regarding a patent that I was an inventor on.
Q. Did the general subject matter involve your work that you had done that led to the patent?

MR. BONELLA: He said it was excerpts. Now you just said it was his notebook. I'm not sure all the pages are here.
MR. SABER: All I can tell you is this is what was produced to us.
THE WITNESS: I see.
MR. SABER: There was another document that was produced to us which were just selected pages from this, but that's not this.
A. I see.
Q. What I gave you was what was produced to us.
MR. BONELLA: I just don't know if it's the whole thing or just selected pages that was relevant.
Q. You testified earlier about names for projects.
A. Correct.
Q. Did you have a name for this project that resulted -- of the work that led to the 446 patent?
A. I don't believe that that would have fallen under a single name.
Q. Okay.
A. But some of the names would have been STS and CBE -- CBE, composite braid evaluation. Yeah,

I would say those are the two that come to mind.
Q. Okay.
A. Maybe one other would be -- no. I think that -- I was trying to -- I thought there was a program name for an improved silk suture.
Q. What was composite braid evaluation? Is that a name that you gave?
A. Yes.
Q. And what did you use that name for?
A. I used that when I was reporting out my work to management, because this was a technology that we developed that -- that was initially developed kind of outside of a particular project.
Q. Uh-huh. But if I understood your testimony correctly, composite braid evaluation doesn't cover all of the project that led to the 446 patent -- of your work, at least.
A. Right. Right.
Q. Does it -- does it refer to some part of your work?
A. It does refer to part of the work, yes.
Q. Well, which part of the work does it refer to?
A. It refers specifically to the -- the evaluation of specific braid constructions that

demonstrate feasibility of the concept.
Q. Well, what does the STS stand for? What does STS stand for?
A. I wish I -- I do not recall.
Q. What?
A. I do not recall.
Q. Okay.
A. I was trying to remember that.
Q. The STS part of -- did you come up with the name STS?
A. No.
Q. Who came up with that one?
A. STS was a program that existed when I had joined.
Q. Do you know who came up with that?
A. No, it just predated me.
Q. What was the STS part of the project?
A. I believe that the initial work by Al Hunter and Art Taylor with the PTFE composites were part of this STS program.
Q. Okay.
A. And I believe, again, I believe it related to some type of silk.
Q. Excuse me?
A. Some -- I believe it related to a

synthetic silklike material.
Q. Synthetic silk --
A. Yeah, silk.
Q. Okay.
A. In the sense of a suture that would -- may be a next-generation product beyond silk.
Q. What were the -- what were -- was the STS part a composite braid?
A. There was -- I believe there was a component of the STS program that involved composite braids.
Q. And what materials?
A. I believe that included PTFE and PET.
Q. Okay. Anything other than that?
MR. BONELLA: Are you talking about before he started? I mean, your questions just aren't clear at all as to what time frame you're talking about.
Q. I'm not talking about any time frame.
MR. BONELLA: STS refers to the entire program.
MR. SABER: There was a project. He's telling me about the project.
MR. BONELLA: But he has it in his notebook. Are you saying before --

to see which ones were relevant, and we produced the ones that -- things that were relevant and not privileged.
MR. SABER: We don't need to take any time, and it may be everything is there.
MR. BONELLA: I'm telling you we searched. We did it.
MR. SABER: I understand, but he identified a specific kind of document.
MR. BONELLA: We looked in those reports.
MR. SABER: Sometimes those things fall through the cracks, and sometimes they don't.
MR. BONELLA: I know exactly what he's talking about, and we looked. That's why I'm telling you we pulled the stuff. We had a report summary, said, Here's the reports from Doctor Steckel from that time frame for Mr. Hunter, for Mr. Taylor; we pulled the reports that were there, we produced the ones that were relevant and things that weren't privileged. So, I know that was specifically done and looked for.
MR. SABER: Okay.
MR. BONELLA: So that's all I can tell you. I'm just saying we did it.
MR. SABER: Again, I'm not trying to

question your bona fideness. If it's done, it's done.
A. These are paper copies. I mean, you know, these were probably hand typed. So, it was one copy in a file somewhere -- if it still exists.
Q. Am I correct that the only combinations that are reported here are PET and PTFE, PET and PP, and then an absorbable, PVS, and vicryl?
MR. BONELLA: Object to the form.
A. We're referring to the 6688 pages?
Q. Yes, sir.
A. That is correct.
Q. Four types of braiding have been discussed, am I correct?
A. Correct.
Q. The first one is carrier braiding. Could you explain what carrier braiding is.
A. When you would have a dissimilar fiber or yarn on separate carriers of the braid.
Q. And would -- on each carrier, would the yarn be homogenous?
A. Yes, there would be only one type of fiber on each carrier.
Q. And what is yarn blending?
A. Yarn blending is when the individual yarns

have already been plied together, so you would have two dissimilar fibers twisted together into a yarn, and then on each carrier, you would have more than one fiber type.
Q. What is plying together?
A. Plying together is a textile term for a twisting operation where you take one or -- well, take more than one yarn, twist them together to form a larger yarn.
Q. Which is -- and it's plied together because it's twisted.
A. Plied. Yeah, is referring to the twisting.
Q. Okay. So, then looking at the little picture that's shown next to No. 2 there --
A. Yes.
Q. -- where it says, the "A, B," is that representing the fact that A and B is twisted together?
A. Correct. That's a yarn bundle, which is made from A type yarn and B type yarn twisted together.
Q. Right. And the A -- B would be from above PET/PTFE or PET/PP, or I guess could be -- let's talk about the --

A. Right, those are the --
Q. -- nonabsorbables.
A. -- examples we used, yes.
Q. At this time were you working with any other materials other than the ones referenced on this page --
MR. BONELLA: Object to form.
Q. -- for this project?
A. On this particular project?
Q. Yes, sir.
A. Well, we were looking at a variety of materials. These are the ones we believed were representative of the invention at the time.
Q. Right.
A. An example -- the most -- the most -- that were exemplary of the invention but not exclusive.
Q. Did you -- at this point did you try to build any other combinations of materials other than PET/PP or PET/PTFE, and I'm talking about -- for purposes of this one -- let's talk about the nonabsorbables.
A. Right. At this stage we auditioned others but did not try to produce prototypes of any.
Q. At any point in the stage of this project, did you try to build anything other than either

Page 190

would be an acceptable suture?
MR. BONELLA: Objection. Asked and answered.
A. We had a belief that it could lead to -- as you're saying -- an acceptable suture. There were other issues that we didn't know. For example, how the -- how polyethylene behaved in the body. So, it was a high priority. Polyethylene, even though there was an interest, it wasn't a -- it wasn't something that was a high priority at the time.
Q. The thought didn't cross your mind that, Oh, this would make an unacceptable suture to put Dyneema together with PET?
A. My recollection was -- an unacceptable suture or an acceptable?
Q. An unacceptable suture.
A. Well, the concern with any of the very high-strength fibers was always knot strength, and that was true whether it was Dyneema, Spectra, Kevlar, etcetera. So, the general view was, I mean, all of those -- 100 percent, all of those, Ethicon evaluated at one point as a suture material. They're the world's biggest suture material company. And all of them there was an

Page 191

interest in how do you improve the knot strength of them, and can you -- that was -- that was something we discussed.
Q. I'm not sure I understand your answer.
A. Go ahead.
Q. And I'm trying to --
A. Sure.
Q. When you had this idea that you could blend Dyneema together with PET, were you -- did you believe it would make an acceptable suture or an unacceptable suture?
A. No. We believed -- we believed that that could offer a suture with straight tensile that was better than Ethibond, and you know, could potentially solve the knot issues, and again, that was a generic view for all of the high-tenacity fibers.
Q. You thought it was a good idea --
A. Yes. Yes.
Q. -- rather than a bad idea?
A. No, we viewed -- we viewed that as a potential good idea.
Q. And you didn't think, Oh, that's a bad idea.
MR. BONELLA: Objection. Asked and

Page 192

answered.
A. I don't know if it was good or bad. You know, it was --
Q. You thought it was a good idea?
A. We thought we could have improved knot strength, and we could get the beneficial properties of both in a blend. That's what we thought.
Q. Okay. Is there any documentation of using Dyneema or Spectra, blending it together with another component -- another -- a yarn -- is there any documentation that exists that you know of?
A. I haven't -- I haven't seen any. I am not aware of any.
Q. Do you know whether that was in your idea memo?
A. I do not know. I have not seen my idea memo.
MR. BONELLA: He said he doesn't know if he did.
THE WITNESS: I'm sorry.
MR. SABER: Actually, he did. He testified he does remember doing it, but that's okay.
Q. Could you look at the Claim 1 of the 446

Page 193

patent, please. And I want to talk about Group A and the Group B.
A. Okay.
Q. Other than PET and PP or PET and PTFE, is there any documentation that you know of that exists of any other combination of one yarn from the first group and one yarn from the second group?
MR. BONELLA: Object to the form of the question.
A. The only documentation that I can speak with any confidence is -- is this. I mean, it's just been too long.
Q. I'm just asking you to do the best you can.
A. Yeah, of course. So, I mean, I can't speak with any confidence that there's documentation that shows any other combination.
Q. Do you --
A. My recollection was --
Q. Go ahead.
A. -- to show the concept we focused on PET and PTFE, and PET and polypropylene. We thought that it would demonstrate the concept. Some of these materials, as you may know, are not readily available in the form that we would need. You

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS
DAY II

TRAVEL TRANSCRIPT

DePUY MITEK, INC., Plaintiffs,	)
vs.	)
ARTHREX, INC., a Delaware corporation, Defendants.	)

CONTINUED DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Hilton Hotel, 25 Allied Drive, Dedham, Massachusetts, on Friday, 3 February, 2006, commencing at 9:06 a.m.

Page 218

A. If I could ask for a clarification.
Q. Sure. Of course.
A. Is that question -- are you asking any -- any of the subject matter discussed?
Q. Well, let me ask particularly about the first paragraph, the issues of conception and reduction to practice of the invention.
MR. BONELLA: You can answer yes, no, or you don't remember.
Q. That's all I'm asking for.
A. The answer is yes.
Q. Okay. Do you see where it says in the first sentence that the invention was reduced to practice at least as early as February 2, 1989 at Ethicon, Inc.?
A. Yes.
Q. Do you agree with that?
MR. BONELLA: Object to the form.
A. I agree to that based on my review of my -- my notebook.
Q. Do you know of any evidence of whether there was a reduction to practice of the invention earlier than February 2, 1989?
A. We had actually produced some braids in the June time frame of 1988. The full

Page 219

characterization didn't occur until the following year.
Q. And what do you mean by "full characterization"?
A. The testing to determine its performance relative to our sutures.
Q. Okay. Using then that as a -- as a description, do you know of any evidence of where you built a braid and tested its performance as you just described prior to February 2, 1989?
A. Can I review my -- my notebook?
Q. Well, if you can answer yes or no. I'm not trying -- I want to try and get you out of here as best we can.
A. Sure.
Q. But I mean, to the extent you can answer the question --
A. Well, to the extent I can answer the question, it would be -- I can't remember.
Q. Okay. As you sit here today, based upon review that you've done, do you have any recollection of a reduction to -- of a -- where you built a braid and tested it as you described prior to February 2, '89?
MR. BONELLA: Object to form.

Page 220

A. I do have recollection of building braid and doing our basic suture testing. The full characterization in terms of some of the more unusual properties took longer.
Q. What -- what do you mean by basic characterization versus?
A. Basic characterization, whenever we made braids, we would test straight tensile, knot tensile, diameter.
Q. Okay.
A. That was the first thing we always did.
Q. So, your recollection is you might have done that prior to February 2, 1989, the --
A. Yes.
Q. -- tensile knot strength and diameter?
A. Correct. That was very quick and outstanding procedure for us.
Q. What did you mean when you said the more full investigation?
A. More full -- we were interested in characterizing this suture pliability, and the methodology for that was still evolving at that time.
Q. And do you recall doing that more full investigation prior to February 2, '89?

Page 221

A. I don't remember completing that before February '89.
Q. Okay. Could you take a look again at Defendant's Exhibit 75, which was marked at your previous deposition, and I'd like to draw your attention to the entry for February 2, '89, which starts on Page 2635. That's the Bates number.
A. 2635.
Q. It's about --
A. Yeah, I've got it.
Q. Somewhere in the middle.
A. Got it.
Q. And that is an entry that goes on for four pages. Is this an entry that shows the more full investigation that you just described?
A. Yeah, this is actually beyond that. This is actually taking our original June constructions and expanding those in the area -- one particular area of PET, PTFE.
Q. And expanding in what way?
A. Attempting to look at multiple configurations and a set of controls -- nonheterogeneous controls.
Q. And then to do what?
A. And then to further the development

Page 222

process and optimize the construction.
Q. Did this involve testing characteristics beyond the basic ones that you -- you told me about of diameter, tensile strength, and knot strength for the heterogeneous braids?
A. Uh-huh. Yes.
Q. And is that on the bottom of -- is that reported -- those results reported on the bottom of Page 2637 under "composite braid evaluation, physical property characterization"?
A. Yes.
Q. Let me just ask you, if I could, the -- am I correct that the -- the heterogeneous braids that are discussed in this report are a combination of PET and PTFE?
A. Yes.
Q. And there are no other ones -- no other composite braids that are discussed other than PET and PTFE, is that correct?
MR. BONELLA: Object to form.
A. Not in this series.
Q. That's -- that's right. And could you describe to me, in a general sense, how the braids were constructed. And I'm talking specifically about the heterogeneous braids.

Page 223

A. The braids consisted of three configurations, a carrier blend, a yarn blend, and a commingled fiber with two -- two versions of the yarn blend.
Q. And that's what we discussed the last time about carrier blending, yarn blending, commingle --
A. Same terminology, yes.
Q. Same things we talked about. So, they were -- they were braided in three different ways.
A. Yes.
Q. And they were braided in the manner in which you described in your last deposition for the three types of braiding?
A. Yes.
Q. What was done next after the braid? Was anything else done after the braid?
A. Conventional -- yes, conventional braid technology is, post braiding you go through a -- some type of hot stretch treatment, and these were -- these were processed by hot stretch.
Q. What is the purpose of a hot stretch?
A. Purpose of the hot stretch is primarily to condense the braid into the smallest diameter uniform bundle possible.
Q. And why are braids hot stretched?

Page 224

A. In my opinion, braids are hot stretched to maximize mechanical strength and to minimize braid roughness.
Q. And is that a step that you felt was appropriate for all of the composite braids that you were working with, the hot stretching step?
A. That was -- that was a step that was appropriate for essentially any braided suture that I was aware of at the time.
Q. Okay. Was there anything else done to process the braids after the hot stretching?
A. Routinely we would go through a cleaning or a scouring operation and these were scoured.
Q. Anything else? What is scouring?
A. Scouring is -- is a washing in a water-based detergent to remove any of the machine oils from processing.
Q. Any other steps taken to the braids?
A. Not -- not in this series.
Q. Were there braids annealed?
A. I have no recollection, and it's -- there's no mention of it in my notebook.
Q. Okay. Were they -- were the braids coated?
A. Not in this series.

Page 225

Q. Were the braids -- was a tipping put on the braids?
A. There would not be tipping, since we never intended to attach needles to this evaluation.
Q. Were the braids sterilized?
A. Typically at this level -- the answer is, I believe, no. At this point in an evaluation, we would typically evaluate presterile properties.
Q. Okay. Could you turn to Page 2638. So, the fourth page of the --
A. Yes.
Q. -- fourth page of this -- the entry. Under "Discussion," the first sentence says, "From a braid processing viewpoint, the commingled yarn was the least problematic braid, followed by the yarn blend. The carrier blend presented the most difficulties in core popping and braid looseness."
What did you mean by "The carrier blends presented the most difficulties in core popping and braid looseness"?
A. Core popping is a common braid defect. You know, any braid text would -- would cover it. The ability to adjust the tension on the yarn that affects core popping was more difficult with the carrier blend and the yarn blend than the

commingled.
Q. What causes -- I think you mentioned core pop or core popping briefly at the last deposition. What causes core popping?
MR. BONELLA: Object to form.
A. Typically, it is a mismatch in tension between your yarns and the braiding machine.
Q. And did the -- the yarns produced by the carrier blend exhibit this problem of core popping?
A. From my notebook, it appears they did.
Q. All right. What is braid looseness?
A. Braid looseness is the individual yarns within the braid are not packed tightly within the diameter and hence have an undesirable softness and roughness.
Q. And what causes this looseness?
A. Variety of factors in the braiding process, including tension, yarn -- yarn diameter, braiding speed, number of picks per inch.
Q. Now, the braids that you were evaluating on February 2nd, 1989, were these additional braids from the ones that you had -- at least initially -- evaluated back in June of '88?
A. Yes.
Q. Do you know whether the ones that you

evaluated in June of '88 had a core popping and looseness problems?
A. Core popping is something we see on almost every lot of braided suture to some extent. It would be very likely that any -- any of the braids from June 6th or February -- June 6th, '88 or February 2nd, '89 had some level of core popping. It's just a feature that has to be managed by process conditions.
Q. And at least by the February 2 time, am I correct that you had not yet been able to manage the core popping issue?
MR. BONELLA: Object to form.
A. Yeah, I should say that both exercises were showing proof of concept, and that core popping is a manufacturing -- it's -- it's a -- it's an issue that would typically be handled later in the process during -- during manufacturing, development.
Q. My question, sir, was as of February 2nd, 1989, had you been able to handle the core popping problem?
MR. BONELLA: Object to form.
A. Yes, adequately to evaluate the technology.

Q. What do you mean when you say adequate to evaluate the technology?
A. I mean that an infrequent core pop over some length of braid would not prevent us from evaluating the technology.
Q. What do you mean -- what do you mean when you say, "evaluating the technology"?
A. Assessing its performance per the standard and nonstandard suture properties.
Q. Performance for what purpose?
A. Performance meaning mechanical strength, handle, pliability, etcetera.
Q. Is there any reason you know that the core popping was infrequent that you used in your answer -- your previous answer?
A. That -- that is my recollection.
Q. You recall that there was infrequent --
A. Yes.
Q. Does this document say it's infrequent?
A. It does not, and I wouldn't -- you know.
MR. BONELLA: Big document.
Q. Well, I'm talking about the -- the -- just to be more specific, I'm talking about the November -- excuse me -- the February 2nd entries.
MR. BONELLA: The page -- February 2nd

entry, does it say infrequent?
MR. SABER: Yes, sir.
A. (Witness reviews document.)
Q. The four pages that we were discussing?
A. Yeah. Yeah. I was going back to the discussion which was -- oh, yeah. (Witness reviews document.) I believe it's inferred in that first paragraph in the discussion.
Q. And that's where your basis of your statement that the core popping was infrequent? Specifically I'm asking about the carrier blend.
A. Yes, for -- yes, just from -- just from my language that I used here in terms of if -- if it -- if the core popping or looseness was significant, meaning very frequent, it would have been my practice to -- to spell that out clearly.
Q. Okay.
A. And the intent here was just, you know, the -- there was more work that would be required for validation.
Q. Could these braids have been sold as sutures, sir?
A. If you -- yes. If you -- your yield would have been lower than -- than preferred -- than optimal.

Page 230

Q. Even with the core popping problem?
MR. BONELLA: Object to form.
Q. Is that your testimony?
A. That is my testimony.
Q. Okay. How could you sell the suture? How could these be -- sutures be saleable with the core popping problem?
MR. BONELLA: Object to form.
A. I believe if you looked at Ethicon's current production of braided sutures, you would find every braided suture has core popping, and that it's quality controlled -- through quality control, sections that have core popping are removed. But that is a defect that every -- every marketed suture braid possesses.
Q. And your testimony is that the core popping is only infrequent is just your understanding from this first paragraph, is that correct?
MR. BONELLA: Object to form. Asked and answered. Mischaracterizes testimony.
A. Yes, and again, if the core popping was significant, it would prevent -- it would prevent -- it would have prevented further characterization.

Page 231

Q. I'm talking about significant to be able to sell the suture, as opposed to evaluating the performance. Do you understand that?
A. I believe I understand that. And again, my answer would be to sell the suture would require a quality control step where core pops would be removed, which is common practice.
Q. Okay. Do you see in the -- did you ever produce -- in the work that you did -- composite fibers that didn't have a core popping problem?
A. I guess you would have to clarify "problem," because, again, core popping's everywhere.
Q. Where you didn't have to comment about the core popping.
MR. BONELLA: This is from his recollection?
MR. SABER: Yes, sir.
MR. BONELLA: Because there is a document in front of him. This is just without -- no refreshing his memory.
MR. SABER: That's correct.
MR. BONELLA: I just want the record to be clear.
MR. SABER: That's correct.

Page 232

A. From my recollection, the commingled fibers rarely had a core popping.
Q. How about the carrier blends?
A. Again, we're within the definition of what frequency is. Is it -- is it for manufacturing? Is it for evaluation of concept?
Q. Let's say for manufacturing.
A. For manufacturing. And the question would be?
Q. Did you ever produce -- by carrier blend -- sutures that wouldn't have a problem from a manufacturing -- excuse me. Did you ever produce -- let me strike that. With respect to the carrier blends, did you ever produce a heterogeneous braid that didn't have a core popping issue with respect to manufacturing the braids --
MR. BONELLA: Object to form.
Q. -- that you can recall?
A. Yeah. That's a very difficult question for me to answer, because I really didn't have manufacturing responsibilities. This was really research and development. So, I -- I just find that a difficult question to answer.
Q. Let's go back, if we could, to Bates Page 2625.

Page 233

A. 2625.
Q. Yeah, which is a November 11, '88.
A. 2625?
Q. Yes, sir. It's a 11/11/88 entry.
A. Very good.
Q. Near the bottom paragraph you see it says, "The PET/PTFE samples (CBE-01 to 05) had a range of processing problems such as core popping and looseness." Do you see that?
A. Yes.
Q. CBE-01 to 05, what is that referring to?
A. That is referring to the table above the core braid evaluation constructions, 1, 2, 3, 4, and 5.
Q. And what braiding was used for those? And if you need -- you may need to go back to 2618 --
A. I think so.
Q. -- for that.
A. (Witness reviews document.) From -- from my notebooks, the 01 is a carrier blend; the 02 is a yarn blend; the 03 is a commingled fiber.
Q. And then 4 and 5 are just controls, so they're not the blend?
A. They're nonheterogeneous. They're homogeneous.

Page 234

Q. Going back to Page 2625, you said they had a range of processing problems such as core popping and looseness. Is core popping and looseness the same thing that we talked about with respect to the February 2, '89 entry?
A. Yes.
Q. Were there any other processing problems? It says, "A range of processing problems." What is that referring to?
A. Core popping and looseness are the -- the only two properties that I can recall being an issue.
Q. Okay.
A. I think that's my figure of speech.
Q. Could you turn to an entry on December 13, '89, which begins on Bates No. 2665, and then goes on for, I guess, three pages.
A. Yes, 2665, December 13th, '89.
Q. Do you see at the top there it says, "PT --" near the top: "PTFE/PET carrier blends have been found to offer exceptional handling properties for braided suture"?
A. Yes.
Q. Okay. What did you mean by "exceptional handling properties" for a braided suture?

Page 235

A. Could I refresh my memory on this?
Q. Sure. Please do.
A. (Witness reviews document.) I believe I was referring to the improved pliability relative to existing commercial non-absorbable braids.
Q. Were you referring to anything other than pliability?
A. I -- I don't see any -- any reference to anything other than pliability.
Q. The -- could you look at the next page, 2666?
A. 2666, yes.
Q. And there's a discussion of properties. The last sentence there, "The composite braids also ranked better than the silk and Ethibond and knot tie-down, even without a coating." Do you see that sentence?
A. Oh. Yes, of course.
Q. What is -- what were you referring to when you said that, "the composite ranked better in knot tie-down, even without a coating"?
A. Knot tie-down -- is the question what is knot tie-down?
Q. Well, what were you referring to when you said that the composite braid ranked better in knot

Page 236

tie-down even without a coating compared to silk and Ethibond?
A. Typically, we would -- we would evaluate the knot tie-down properties of experimental braids by having a technician who was specifically trained in this test method to do a simulated suture tie involving multiple throws, and make a qualitative assessment on some scale in terms of its relative smoothness and force required for the tying operation.
Q. Are the results of that test reported in -- in your lab notebook?
A. I don't know.
Q. But is it your best recollection that that's the kind of test that you're referring to by the sentence that the, "Composite also ranked better than the silk and Ethibond in knot tie-down even without a coating"?
A. Yes.
Q. Is it pretty typical to do that kind of test we just described?
A. Yes.
Q. To test knot tie-down?
A. Yes. Yes.
Q. It was surprising that the composite

Page 237

ranked better than silk and Ethibond in knot tie-down even without a coating?
A. I believe that was a surprising find.
Q. And is that part of the basis what became -- of what became the invention in 446?
MR. BONELLA: Object to form.
A. Is that part of the basis?
Q. That -- yeah. Let me -- let me rephrase that question. Was this part of the improvement that you were referring to in the 446 patent --
MR. BONELLA: Object.
Q. -- of your suture?
MR. BONELLA: Object to form.
A. (Witness reviews document.) That was not the intention.
Q. Was better tie-down part of the handling improvement that you're referring to in the December 13, '89 entry in your lab notebook?
A. I view knot tie-down -- when you -- I view tie-down as a separate property from handling. So, when I said, "exceptional handling," I was referring to pliability and -- and the qualitative features of hand, but the three knot tie-down properties are subtly different.
Q. They're?

Page 246

A. As it's stated, we're -- where one of the composite braids that two sets of properties we're trying to combine would be strength and lubricity.
Q. And is this -- is this sentence referring to the work that we've been talking about today on the composite braid project?
A. Yes, in part.
Q. I don't quite understand that. I'm talking -- focusing just on that first sentence. What did you mean when you said, "Yes, in part"?
A. Yes. That the constructions that we had looked at, some of those were this particular embodiment that included a high lubricity and a high strength.
Q. And which one was -- which fiber gave the high lubricity? Well, strike that. What -- what components were you talking about when you wrote this sentence?
A. Which components was I talking about?
Q. Yes, sir.
A. Which yarns.
Q. Blending of two fiber components.
A. Right. Clarification: Of the previous constructions we discussed which component?
Q. Well, I'm trying to find out what two

Page 247

components you were referring to in this -- in this paragraph.
A. Well, in the previous -- previous discussion, the polyester provided the high strength, and the PTFE provided lubricity.
Q. Is that what you're referring to in this -- in this paragraph?
A. These aren't PTFEs. These are another fiber system blend.
Q. Well, is it -- that's what I'm trying to figure out. Is this first paragraph -- the title of the project says, "BCF-CBE."
A. Right.
Q. Is that referring to two different --
MR. BONELLA: Object --
Q. -- projects?
MR. BONELLA: Object to form. Misstates the document.
A. That is referring to the one embodiment of the original description of the heterogeneous braids being by component fiber, so that this was one subset of that original idea.
Q. The "by component fiber" being that fourth thing that we talked about before?
A. Exactly. Exactly.

Page 248

Q. The copolymers?
A. Exactly. Co-extrusion at the fiber level.
Q. Right. But what's talked about here in the background is -- is that talking about the co-extrusion, or is that talking about the carrier blends that we've been talking about?
MR. BONELLA: Wait a second. Let me read the question.
MR. SABER: Let me rephrase it.
MR. BONELLA: Okay.
Q. The discussion in the background, is that referring to the co -- copolymer extrusion that you just described?
MR. BONELLA: Object to form.
A. I'm sorry. Could you repeat the question.
(Question read back.)
A. I believe that the background is applying to the broader case of carrier blends, yarn blends by component, etcetera.
Q. Oh. So, this is a more generalized discussion that could apply to any of the four methods that we talked about last week?
A. Well, we -- we clearly did explore those four, yes.
Q. Okay.

Page 249

A. We send one that has been -- one type that has been explored is this combination of high lubricity and high strength.
Q. Right. And what were -- specifically were you referring to when you said the one type of composite braid which has been explored? Is that referring to the PTFE/PET braids that we've discussed today?
MR. BONELLA: Object to form. Misstates the document.
A. I don't know what I was thinking.
Q. Okay.
A. When I -- you know, what I was referring back to back in March of 1990.
MR. SABER: Mark this with the next exhibit number.
(DMI095020 marked Exhibit 78.)
Q. Let me show you what's been marked as Defendant's Exhibit 78 and ask you if you're familiar with this.
A. (Witness reviews document.) No.
Q. You've never seen this document before?
A. No recollection.
Q. Okay. Are you familiar with the subject matter of this document?

Page 250

A. Yes.
Q. And what is it – what is that?
A. Well, I'm familiar that this was the feedback from the idea review board, the standard form, and from the note on it, I assume the 27 – Idea No. 2749 was the heterogeneous braid idea.
Q. In fact, just on that point: Could you take a quick look at Defendant's Exhibit 76 that was previously marked, and see it says the same –
A. Yes.
Q. – IM number? So you feel certain that this is referring to –
A. Yeah.
Q. – your project – your idea memo?
A. Yes.
Q. Okay.
A. And that Barbara Schwartz, who was my manager at the time, was recommending it for the IRB to pursue some type of IP on that idea.
Q. Who is Barbara Schwartz?
A. Barbara Schwartz was either manager or director of suture research at the time and someone that I reported up through.
Q. Okay. Is this her note that's –
A. It appears to be her note, yes.

Page 251

Q. Could you read her note for the record, please.
A. Yes. "Being reviewed as potential new product for Ethicon. May offer significant advantages if technical problems of mixing of materials with dissimilar stress/strain properties can be overcome."
Q. Okay. Do you have an understanding of what was meant by "-- if technical problems of mixing of materials with dissimilar stress/strain properties can be overcome"?
A. I believe she's referring to the tension issues on processing the heterogeneous yarns.
Q. That we've discussed last week and earlier today?
A. That would be my understanding.
Q. All right. And is it your understanding that those –
A. Although this is Barbara's words, not mine.
Q. That's what I'm trying to under – to get your understanding.
A. Yeah.
Q. And is it your understanding that those technical problems with tension had not yet been

Page 252

overcome as of February 8th, 1990?
MR. BONELLA: Object to the form.
A. I don't know if -- if Barbara at the director level or manager level would have had firsthand knowledge of that, so --
THE WITNESS: I'm sorry. Could you repeat the question.
(Question read back.)
A. Once again, I think we're in the realm of manufacturing requirements versus proof of concept requirements in terms of have the technical problems been overcome?
Q. Well, was it your understanding that – well, do you understand – do you know the basis of Ms. Schwartz's comment, what that was based upon – what her comment was based upon?
A. No, I'm inferring it from -- from the comments and from what we've read.
Q. Okay. So, do you have an understanding one way or another exactly what she was talking – well, strike that.
MR. SABER: Why don't we take our break.
(Recess was taken.)
Q. Doctor Steckel, there came a time, of course, when Ethicon applied for the 446 patent, of

Page 253

which you're one of the named inventors. What do you recall about the – your involvement in the process of applying for that patent?
MR. BONELLA: And you can talk about facts, but if you had communications with attorneys, that's attorney/client privilege. You shouldn't talk about the substance of communications that you had with attorneys in developing it, but you can talk about facts about, you know, general facts as to what your involvement was.
Q. You know, if I may just clarify Mr. Bonella's remarks, at least for purposes of this question, I would want to hear about contacts that you had with attorneys, though at least for purposes of this question, you don't have to tell me about the substance of any such contacts.
MR. BONELLA: You can tell him who, what, where, when.
THE WITNESS: Right.
A. Well, I mean, my overall recollection is fairly vague. I worked with -- the "who" was Matt Goodwin and Rick Skula were the attorneys at Ethicon at the time, although I worked on a couple of different applications, but I believe Matt and

HERMES DECLARATION
EXHIBIT 7 – PART 1 OF 2

BOOK NO. 2175

ETHICON, INC.
a Johnson-Johnson company

Issued to Mark Steckel

Covering the Period

Feb 29, 1988 to

EXHIBIT
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TABLE OF CONTENTS

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002606

(For Subject Index, see Pages 251 - 258)

Page ......
Book No. ......
2175

Project No. 16211 - STS Experiment No. - Date 3/31/88

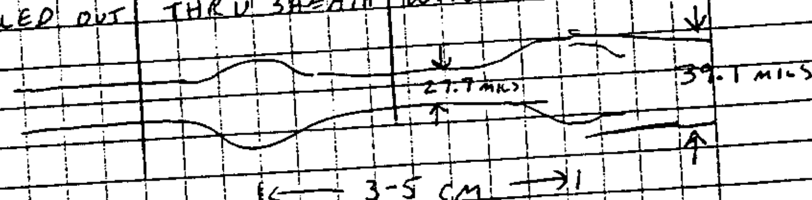
Subject STS - PTFE BRAIDS - REPLICATION OF A. HUNTER'S STS CONSTRUCTIONS

Purpose TO VERIFY THE MANUFACTURING CONDITIONS FOR THREE STS BRAID CONSTRUCTIONS (SIZE 2/0, 0, 2) WHICH WERE DEVELOPED BY A. HUNTER.

NOTEBOOK #	2175-1A	2175-1B	2175-1C
EXPERIM. # (D. REMBERT)	STZ-001	STZ-002	STZ-003
START DATE	3/28/88	3/28/88	3/28/88
BRAIDER #	1	00	3
SIZE	2	0	2-0
YN COLOR/DEX.	PTFE / WHITE	PTFE / WHITE	PTFE / WHITE
CONSTRUCTION	16 x 3	12 x 1	8 x 1
PICK GEAR	40	31	42
BRAIDER RPM	100	~~100~~ (9 YDS/HR)	~~100~~ 9 YDS/HR
SHEATH LOT #	225-30-0 - TI143	225-30-0 TI143	225-30-0 TI143
SHEATH CONSTRUC.	1/0 225 DEN	225 DEN x 1/0	225 DEN x 1/0
SHEATH DESCRIP	PTFE MULTIFIL DUPONT	PTFE MULTI (DUPONT)	PTFE MULTIF. (DUPONT)
CORE DESCRIP	PTFE MULTIF. (DUPONT)	PTFE MULTI (DUPONT)	PTFE MULTIF. (DUPONT)
CORE LOT #	225-30-0 TI143	225-30-0 TI143	225-30-0 TI143
CORE CONSTRUC.	1/3 450 DEN	1/0 225 DEN	225 DEN x 1/0
SHEATH TENSION SPRING	0.011 x 5 1/2 GRN	0.009 x 5" NAT	0.009 x 5" NAT
CORE TENS SPRING	0.011 x 5 1/2 GRN	0.009 x 5" NAT	0.009 x 5" NAT
TEN DEV (CORE)	BUTT CARRIER	BUTT CARRIER	BUTT CARRIER
QUANTITY	480 YDS	500 YDS	760 YDS

COMMENTS:

2175-1A: RANDOM MODULAR GEOMETRY VISABLE WITH NAKED EYE AT 3-5 CM INTERVALS APPARENTLY DUE TO "CORE-POPPING" (CORE CAN BE PULLED OUT THRU SHEATH WALL AT NODE).



MICRO EVAL (25X): A GREAT DEAL OF ENTRAPPED BLACK CONTAMINENT, V. ~~LITTLE~~ FEW BROKEN FILAMENTS

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C.A. No.04-12457 PBS
DMI002607

Investigator [signature] Date 4/14/88

Witness Crawford Britt Date 3-15-90

No. 2175

Project No. CONT. FROM PREVIOUS PAGE Experiment No. Date

Subject

Purpose

2175-1B: VISUAL BUMPY SURFACE. MICRO EVAL (25X) - ONE CARRIER IS CONSISTENTLY BUCKLED OUT OF BRAID STRUCTURE.

2175-1C: VISUAL - SLIGHTLY IRREGULAR SURFACE. MICRO EVAL (25X) - BRAID SOME WHAT LOOSE - ESPECIALLY ONE OR TWO CARRIERS WHICH OCCASIONALLY SLIGHTLY BUCKLE OUT OF PLANE. BRAID APPEARS FACETED DUE TO 8 CARRIER CONSTRUCTION.
OPTIC DIAM: 17.0 MIL

GENERAL OVERALL COMMENTS: BRAID PROCESS CONDITIONS REQUIRE OPTIMIZATION.

MS 3/31/93

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DMI002608

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Page ....
Book No. ....
2175

Project No. 16211 - STS Experiment No. .... Date 3/31/88

Subject PROCESS CHANGES FOR STS BRAIDS

Purpose TO OBTAIN HIGHER QUALITY BRAID STOCK FOR STS SIZES 2, 2/0, AND 0 BY ADJUSTING CARRIER TENSIONS ON BRAIDER. PREVIOUS PROCESS CONDITIONS REPORTED BY A. HUNTER RESULTED IN CORE-POPPING AND OTHER BRAID DEFECTS (2175-1A, 1B, 1C).

NOTE: ALL BRAID PROCESS CONDITIONS SAME AS 2175-1A, 1B AND 1C EXCEPT FOR:

NOTEBOOK #	2175 - 3A	2175 - 3B	2175 - 3C
EXPER #	STZ-004	STZ-005	STS-006
START DATE	3/31/88	3/31/88	3/31/88
SHEATH TENSION SPRING	0.011 x 5½ GN	0.009 x 5 NAT	.009 x 5" NAT
CORE TENSION SPRING	.012 x 5½ OR	.011 x 5½ GN	.011 x 5½ GN
OTHER CHANGES		ONE CARRIER REMOVED AND CLEANED (TENSION MECH STICKING), CHANGE ALL SPRINGS, 3 BOBBINS CHANGED	NEW SPRINGS, CHANGE 4 CARRIERS, CLEAN BRAIDER

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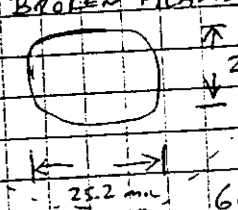
COMMENTS:

2175-3A: HIGHER CORE TENSION ELIMINATED CORE-POPPING OBSERVED IN 2175-1A. GOOD QUALITY (25X), GOOD CIRCULAR GEOM. SOME TRASH OPTICAL DIAM - 27.1 MIL

2175-3B: GOOD QUALITY, SMOOTH. MICRO EVAL (25X): SOME OCCASIONAL LOOSENESS AND BROKEN FILAMENTS. BRAID SOMEWHAT RECTANGULAR IN X-SECT: IMPROVEMENTS PROBABLY DUE TO CARRIER CHANGES + CLEANING



2175-3C: IRREG SMOOTHNESS. GOOD QUALITY BUT SQUARISH X-SECT DUE TO PACKING CHAR OF 8 CARRIER CONSTRUCTION WITH THIS YARN. OPTICAL DIAM: 17.6 MILS

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Witness Crawford Britt Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002609

Page
Book No.
2173

Project No. 16211 - STS Experiment No. Date 4/15/88
Subject DIE - DRAWING TRIALS OF STS PTFE BRAIDS / INCOMING YARN VARIABILITY
Purpose

PROCEDURE: DIE - DRAWING OF PTFE BRAIDS PERFORMED PER AL HUNTER'S "PROCESS TRANSFER MEMO OF STS SUTURES" OF 10/29/87, SUCH AS (1) BRAID WAS DRAWN THRU STEEL WIRE DIES, (2) BRAID WAS SIMULTANEOUSLY BEING HOT-STRETCHED USING GODET SET-UP AND A FORCED CONVECTION TUNNEL OVEN AT 315°F, AND (3) MULTIPLE PASSES WITH DECREASING DIE SIZE.

RESULTS

- DIE - DRAWING SIGNIFICANTLY REDUCES THE BRAID PROFILE OF THE PTFE BRAIDS IN ALL CASES IN THE "UNPETURBED" OR RELAXED CONDITION. HOWEVER, A LOW AMOUNT OF TORSION OR EVEN BENDING OF THE SUTURE TYPICAL OF THE MANIPULATION REQUIRED FOR KNOT TIE - DOWN RESULTS IN AN DRASTIC OPENING UP OF THE BRAID STRUCTURE. THUS, THE BRAID STRUCTURE IS APPARENT IN USE ALTHOUGH IT APPEARS 'MONOFILAMENT-LIKE' IN THE RELAXED CONDITION.

- PRODUCT UNIFORMITY (DIAMETER) IS CRITICAL IN THE DIE - DRAWING OPERATION WITH THE RISKS OF FREQUENT LINE BREAKAGE ~~AND~~ (OVERSIZED ~~LARGE~~ REGIONS) AND ROUGH (UNDERSIZED REGIONS) FOR VARIABLE MATERIAL. THIS MOST LIKELY RESULTS FROM THE APPARENT LARGE VARIATIONS IN YARN DENIER (AND DIAMETER) OF THE DUPONT TEFLON YARN. TYPICAL DEVIATIONS WERE:

DUPONT LABELED DEN	ETHICON MEAS. DEN
66	88
64	83
88	102

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C.A. No.04-12457 PBS
DMI002610

Investigator [signature] Date 4/15/88
Witness [signature] Date 3-15-90

Page ......
Book No. ......
2175

Project No. BRAID EQUIP Experiment No. IDEA Date 4/18/88
Subject NOVEL BRAIDING EQUIPMENT FOR SUTURE MANUFACTURE
Purpose DOCUMENT CONCEPTS RELATING TO SIMON DE YOUNG M/C

IDEA: SIGNIFICANT IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY BE ACHIEVED BY UTILIZING A NOVEL BRAID MECHANISM OFFERED SIMON DE YOUNG CO. THE MECHANISM IS BASED ON THE FOLLOWING FEATURES: (1) CARRIERS RESIDE ON TWO HORIZONTAL PLANES VS. ONE FOR CONVENTIONAL BRAIDERS, (2) CARRIERS MOVE IN CIRCULAR PATH VS. SERPENTINE PATH FOR CONVENTIONAL BRAIDERS, AND (3) INTERLACING OCCURS BY DIVERSION OF STRAND PATH OF LOWER PLANE OF CARRIERS BY A MOVING YARN GUIDE.

IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY INCLUDE:

1) LONGER PROCESS RUNS — CARRIER PACKAGE DIAMETER IS INCREASED SINCE CARRIERS RESIDE ON 2 PLANES WHICH ALLOWS MORE YARN / BOBBIN. LARGER BOBBINS → MORE ECONOMICAL SINCE LESS SET-UP TIME

2) HIGHER BRAIDER SPEEDS — DUE TO CIRCULAR CARRIER PATH VS SERPENTINE. MORE ECONOMICAL + SHORTER EXPOSURE TIMES FOR ABSORBABLE MATERIALS.

3) IMPROVEMENT IN BRAID UNIFORMITY — MORE CONSTANT YARN TENSION DURING BRAIDING SINCE DISTANCE FROM BOBBIN TO BRAIDING PT REMAINS CONSTANT THROUGHOUT REVOLUTION (VS SERPENTINE PATH + FLUCTUATING TENSION). TRANSLATES TO IMPROVED SMOOTHNESS + HAND

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002611

Investigator [signature] Date 4/18/88
Witness Crawford Britt Date 3-15-90

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Project No. IFI Experiment No. ______ Date 5/12/88

2175 Subject DEFINE CONSTRUCTIONS AND YARN INFO FOR IFI BRAIDS

Purpose IFI CONSTRUCTIONS + YARN INFO

BACKGROUND: A CONCEPT WAS FOWARDED BY DR. E. BROYER + SUTURE DEVELOPMENT TO PRODUCE A MONOFILAMENT LIKE SUTURE BY BRAIDING 2 DIFFERENT POLYMER FIBER TYPES WITH A DIFFERENTIAL IN Tm AND SUBSEQUENTLY MELTING THE LOWER Tm FIBER TO FORM A MATRIX AROUND THE HIGHER Tm FIBER REINFORCEMENT. WORK IS TO BE PERFORMED IN CONJUNCTION WITH THE ISRAELI FIBER INSTITUTE (IFI)

PURPOSE: DEFINE BRAID CONSTRUCTIONS AND DOCUMENT YARN LOT INFO FOR IFI BRAIDS. TWO TYPES OF BRAID COMPOSITES ARE SUGGESTED BY DR. BROYER: 1) ROOT BRAIDS — CORE & SHEATH ARE DIFFERENT FIBERS AND 2) RMF OR "REINFORCED MONOFILAMENT" WHERE THE 2 FIBERS ARE CARRIER BLENDED IN THE CORE + SHEATH.

IFI BRAID CONSTRUCTIONS TO BE PROCESSED INCLUDE:

IFI BRAID CONSTRUCTIONS

IFI-	FIBER 1 TYPE	FIBER 2 TYPE	SHEATH X CORE CARRIERS	SHEATH FIB 1 DENIER	SHEATH FIB 2 DENIER	CORE FIB 1 DENIER	CORE FIB 2 DENIER
1	VIC	PDS	8X3	28	*	*	60
2	VIC	PDS	4X5	52	*	*	48
3	PET	PP	4X3	40	*	*	86
4	VIC	PDS	8X3	56	*	*	60
5	VIC	PDS	12X5	28	*	*	60
6	PET	PP	8X3	40	*	*	100
7	PET	PP	8X3	30	20	70	*
8	PET	PP	12X3	20	20	55	*
9	VIC	PDS	8X1	52	24	*	60
10	PET	PP	8X3	20	20	55	60
11	VIC	PDS	12X1	28	24	*	60
12	VIC	PDS	8X1	28	48	52	*
13	PET	PP	8X3	20	20	*	100
14	VIC	PDS	12X3	14	24	14	48
15	PET	PP	8X3	20	*	*	86

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C.A. No.04-12457 PBS
DMI002612

MS 5/12/88

Investigator [signature] Date 5/12/88

Witness Carolann Britt Date 3-15-90

No.
175

Project No. 16211 - STS Experiment No. Date 4/15/88

Subject DIE - DRAWING TRIALS OF STS PTFE BRAIDS / INCOMING YARN VARIABILITY

Purpose:

PROCEDURE: DIE - DRAWING OF PTFE BRAIDS PERFORMED PER AL HUNTER'S "PROCESS TRANSFER MEMO OF STS SUTURES OF 10/29/87, SUCH AS (1) BRAID WAS DRAWN THRU STEEL WIRE DIES, (2) BRAID WAS SIMULTANEOUSLY BEING HOT-STRETCHED USING GODET SET-UP AND A FORCED CONVECTION TUNNEL OVEN AT 315°F, AND (3) MULTIPLE PASSES WITH DECREASING DIE SIZE.

RESULTS

- DIE - DRAWING SIGNIFICANTLY REDUCES THE BRAID PROFILE OF THE PTFE BRAIDS IN ALL CASES IN THE "UNPETURBED" OR RELAXED CONDITION. HOWEVER, A LOW AMOUNT OF TORSION OR EVEN BENDING OF THE SUTURE TYPICAL OF THE MANIPULATION REQUIRED FOR KNOT TIE-DOWN RESULTS IN A DRASTIC OPENING UP OF THE BRAID STRUCTURE. THUS, THE BRAID STRUCTURE IS APPARENT IN USE ALTHOUGH IT APPEARS 'MONOFILAMENT-LIKE' IN THE RELAXED CONDITION.

- PRODUCT UNIFORMITY (DIAMETER) IS CRITICAL IN THE DIE - DRAWING OPERATION WITH THE RISKS OF FREQUENT LINE BREAKAGE ~~[illegible]~~ (OVERSIZED ~~LARGE~~ REGIONS) AND ROUGH (UNDERSIZED REGIONS) FOR VARIABLE MATERIAL. THIS MOST LIKELY RESULTS FROM THE APPARENT LARGE VARIATIONS IN YARN DENIER (AND DIAMETER) OF THE DUPONT TEFLON YARN. TYPICAL DEVIATIONS WERE:

DUPONT LABELED DEN	ETHICON MEAS DEN
66	88
64	83
88	102

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C.A. No.04-12457 PBS
DMI002613

Investigator [signature] Date 4/15/88

Witness Date 2-15-90

Page
Book No.
2175

Project No. BRAID EQUIP Experiment No. IDEA Date 4/18/88
Subject NOVEL BRAIDING EQUIPMENT FOR SUTURE MANUFACTURE
Purpose DOCUMENT CONCEPTS RELATING TO SIMON DE YOUNG M/C

IDEA: SIGNIFICANT IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY BE ACHIEVED BY UTILIZING A NOVEL BRAID MECHANISM OFFERED SIMON DE YOUNG CO. THE MECHANISM IS BASED ON THE FOLLOWING FEATURES: (1) CARRIERS RESIDE ON TWO HORIZONTAL PLANES VS. ONE FOR CONVENTIONAL BRAIDERS, (2) CARRIERS MOVE IN CIRCULAR PATH VS. SERPENTINE PATH FOR CONVENTIONAL BRAIDERS, AND (3) INTERLACING OCCURS BY DIVERSION OF STRAND PATH OF LOWER PLANE OF CARRIERS BY A MOVING YARN GUIDE.

IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY INCLUDE:

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2) HIGHER BRAIDER SPEEDS — DUE TO CIRCULAR CARRIER PATH VS SERPENTINE. MORE ECONOMICAL + SHORTER EXPOSURE TIMES FOR ABSORBABLE MATERIALS.

3) IMPROVEMENT IN BRAID UNIFORMITY — MORE CONSTANT YARN TENSION DURING BRAIDING SINCE DISTANCE FROM BOBBIN TO BRAIDING PT REMAINS CONSTANT THROUGHOUT REVOLUTION (VS SERPENTINE PATH + FLUCTUATING TENSION) TRANSLATES TO IMPROVED SMOOTHNESS + HAND

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C.A. No.04-12457 PBS
DMI002614

Investigator [signature] Date 4/18/88
Witness Crawford Britt Date 3-15-90

175

Project No. IFI Experiment No. Date 5/12/88

Subject DEFINE CONSTRUCTIONS AND YARN INFO FOR IFI BRAIDS

Purpose IFI CONSTRUCTIONS + YARN INFO

BACKGROUND: A CONCEPT WAS FOWARDED BY DR. E. BROYER + SUTURE DEVELOPMENT TO PRODUCE A MONOFILAMENT LIKE SUTURE BY BRAIDING 2 DIFFERENT POLYMER FIBER TYPES WITH A DIFFERENTIAL IN T_M AND SUBSEQUENTLY MELTING THE LOWER T_M FIBER TO FORM A MATRIX AROUND THE HIGHER T_M FIBER REINFORCEMENT. WORK IS TO BE PERFORMED IN CONJUNCTION WITH THE ISRAELI FIBER INSTITUTE (IFI)

PURPOSE: DEFINE BRAID CONSTRUCTIONS AND DOCUMENT YARN LOT INFO FOR IFI BRAIDS. TWO TYPES OF BRAID COMPOSITES ARE SUGGESTED BY DR. BROYER: 1) ROOT BRAIDS — CORE & SHEATH ARE DIFFERENT FIBERS AND 2) RMF OR "REINFORCED MONOFILAMENT" WHERE THE 2 FIBERS ARE CARRIER BLENDED IN THE CORE + SHEATH. IFI BRAID CONSTRUCTIONS TO BE PROCESSED INCLUDE:

IFI BRAID CONSTRUCTIONS

IFI-	FIBER 1 TYPE	FIBER 2 TYPE	SHEATH X CORE CARRIERS	SHEATH FIB 1 DENIER	SHEATH FIB 2 DENIER	CORE FIB 1 DENIER	CORE FIB 2 DENIER
1	VIC	PDS	8X3	28	*	*	60
2	VIC	PDS	4X5	52	*	*	48
3	PET	PP	4X3	40	*	*	86
4	VIC	PDS	8X3	56	*	*	60
5	VIC	PDS	12X5	28	*	*	60
6	PET	PP	8X3	40	*	*	100
7	PET	PP	8X3	30	20	70	*
8	PET	PP	12X3	20	20	55	*
9	VIC	PDS	8X1	52	24	*	60
10	PET	PP	8X3	20	20	55	60
11	VIC	PDS	12X1	28	24	*	60
12	VIC	PDS	8X1	28	48	52	*
13	PET	PP	8X3	20	20	*	100
14	VIC	PDS	12X3	14	24	14	48
15	PET	PP	8X3	20	*	*	86

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002615

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MS 5/12/88

Investigator Date 5/12/88

Witness Date 2-15-90

Page ....
Book No. ......
2175

Date 5/12/88
Project No. IFI Experiment No. ....
Subject IFI BRAID CONSTRUCT + YARN LOT ID
Purpose ....

IFI - CONT FROM PG. 6

VICRYL/PDS AND PET/PP COMPOSITES ARE TO BE PROCESSED FROM THE FOLLOWING YN. LOTS:

IFI YARN LOT INFORMATION

IFI #	FIBER 1	FIBER 2	SHEATH FIB 1 DENIER	SHEATH FIB 1 LOT #	SHEATH FIB 2 DENIER	SHEATH FIB 2 LOT #	CORE FIB 1 DENIER	CORE FIB 1 LOT #	CORE FIB 2 DENIER	CORE FIB 2 LOT #
1	VIC	PDS	28	XC3374	*	*	*	*	60	PY-010 60/10
2	VIC	PDS	52	XC3349	*	*	*	*	48	PY-001.3-48/4
3	PET	PP	40	40/27-R14-56	*	*	*	*	86	PP-001-5 5DPF
4	VIC	PDS	56	XC-3371	*	*	*	*	60	RLS-248B-60/5
5	VIC	PDS	28	XC-3181	*	*	*	*	60	RLS-248B-60/5
6	PET	PP	40	40/27-R14-56	*	*	*	*	100	PP002-1
7	PET	PP	30	30-20-R14-56	20	21.4-PP-005	70	70-34-R14-55	*	*
8	PET	PP	20	20-10-RXX-56	20	20.7-PP-004	55	55-27-R02-52	*	*
9	VIC	PDS	52	52-26-C3388	24	24-2-PY-003	*	*	60	60-10-PY-010
10	PET	PP	20	20-10-R02-56	20	PP-004	55	55-27-R02-52	60	PP-003
11	VIC	PDS	28	XC3374	24	PY-37-2-0	*	*	60	PY-010
12	VIC	PDS	28		48		52		*	*
13	PET	PP	20	20-10-R02-56	20	*	*	PP-004	100	PP-003
14	VIC	PDS	14	*	24	*	14	*	48	*
15	PET	PP	20	20-10-R02-56	*	*	*	*	86	PP-001

MS 5/12/88

BRAID PROCESS CONDITIONS, HOT-STRETCH PARAMETERS AND PROPERTIES OF THE IFI BRAIDS WILL BE SUMMARIZED AT A FUTURE DATE

DePuy Mitek, Inc. v. Arthrex, Inc.
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DMI002616

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Witness [signature] Date 3-15-90

75

Project No. COMPOSITE BRAIDS (CBE) Experiment No. Date 6/6/88

Subject COMPOSITE BRAID EVAL - BRAID CONSTRUCTIONS, YARN LOT, IN PROCESS

Purpose

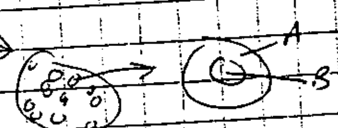
BACKGROUND: A PRELIMINARY EVALUATION OF COMPOSITE BRAIDS, i.e. BRAIDED SUTURES CONSTRUCTED OF TWO OR MORE FIBER TYPES DESIGNED TO REALIZE THE BENEFICIAL PROPERTIES OF EACH POLYMER. COMPOSITES TO BE EVALUATED INCLUDE PET/PTFE, PET/PP AND (ABSORBABLE) PDS / VICRYL. FOUR PROCESS METHODOLOGIES WILL BE EMPLOYED TO: COMBINE THE DIFFERENT FIBER TYPES INTO COMPOSITE BRAIDS:

1) CARRIER BLENDING: BLENDING IS ACCOMPLISHED DURING BRAIDING BY DIVIDING THE CARRIERS INTO TWO SETS WITH YARN A RESIDING ON ONE SET AND YARN B ON THE OTHER.

2) YARN BLENDING: BLENDING IS ACCOMPLISHED PRIOR TO BRAIDING BY PLYING YARNS A + B TOGETHER ~~PRIO~~ TO FORM A COMPOSITE YARN.

3) FIBER COMMINGLING - BLENDING IS ACCOMPLISHED ON FIBER LEVEL BY THE "COMMINGLING PROCESS" (CONCORDIA, RI) IN WHICH FIBERS A + B ARE INTIMATELY INTERMINGLED MOST LIKELY BY AIR-JET

4) BICOMPONENT FIBERS: BLENDING IS ACCOMPLISHED ON THE FIBER LEVEL BY EXTRUSION OF TWO POLYMERS (CONCENTRIC) PER FILAMENT.



THE LEVEL OF BLEND HOMOGENEITY INCREASES FROM 1→4.

Investigator [signature] Date 6/6/88

Witness Date 3-15-90

9
Page
Book No.
2175

Project No. CBE Experiment No. Date 6/6/88
Subject CONTINUED
Purpose

THE INITIAL COMPOSITE BRAID EVALUATION WILL FOCUS ON 15 CONSTRUCTIONS OF PET/PTFE, VICRYL/PDS, + PET/PP BLENDS:

COMPOSITE BRAID EVALUATION
BRAID CONSTRUCTIONS

MGS ID#	COMP TYPE	BRAID TYPE	SIZE	SHxCR CARR.	FIBER A	DEN A	FIBER A VOLUM FRACT	FIBER B	DEN B	FIBER B VOLUM FRACT	FIBER C	DEN C	FIBER C VOLUM FRACT	SH CARR FIB A	SH CA FIB B	CR CARR FIB A	CR C FIB
CBE-01	CB	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-7\0	2-8\E	1-3	1-3
CBE-02	YB	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-8	1-8	1-3	1-3
CBE-03	CF	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-8	1-8	1-3	1-3
CBE-04	CT	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-8	*	1-3	*
CBE-05	CT	CS	X-0	8x3	PET	70		PTFE	75		*	*		*	1-8	*	1-3
CBE-06	CB	CS	2-0	12x1	VICRYL	28	34	PDS	48	66	*	*	*	1-11\0	2-12\E	1	1
CBE-07	YB	CS	2-0	12x1	VICRYL	28	34	PDS	48	66	*	*	*	1-12	1-12	1	1
CBE-08	CF	CS	2-0	12x1	VICRYL	28	34	PDS	48	66	*	*	*	1-12	1-12	1	1
CBE-08A	CF	CS	X-0	12x1	VICRYL	28		PDS	48		*	*		1-12	1-12	1	1
CBE-09	CT	CS	2-0	12x1	VICRYL	28	100	PDS	48	0	*	*	*	1-12	*	1	*
CBE-10	CT	CS	2-0	12x1	VICRYL	28	0	PDS	48	100	*	*	*	*	1-12	*	1
CBE-11	CF	CS	X-0	12x1	PET	70		PP	50		*	*		1-12	1-12	1	1
CBE-12	BF	CS	X-0	12X1	PET/PP	60		*	*		*	*		1-12	*	1	*
CBE-13	CT	CS	X-0	12X1	PET	70		PP	50		*	*		1-12	*	1	*
CBE-14	CT	CS	X-0	12X1	PET	70		PP	50		*	*		*	1-12	*	1
CBE-15	CB	CS	1	12x1	PET	70	51	PTFE	110	49	*	*	*				

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MS 6/6/88

KEY:
CB : CARRIER BLEND
YB : YARN BLEND
CF : COMMINGLED FIBER
BF : BICOMPONENT FIBER
CT : CONTROL

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C.A. No.04-12457 PBS
DMI002618

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Witness [illegible] Britt Date 2-15-90

Page
k No.
175

Project No. CBE Experiment No. Date 6/6/88
Subject CONT
Purpose

YARN LOT INFORMATION FOR CBE 1-15 :

COMPOSITE BRAID EVALUATION
YARN A DESCRIPTION

MS 6/6/88

MGS ID#	FIBER A	FIB A DENIER	FIB A FILAM COUNT	FIB A SOURCE	FIB A LOT #	FIB A COLOR	FIB A TWIST LEVEL (TPI)	FIB A TWIST DIRCT (S/Z)	FIB A ENTANG LEVEL
CBE-01	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-02	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	*
CBE-03	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	*
CBE-04	PET	70	48	SUT DEV	SPX-305	GREN	0.0	*	*
CBE-05	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-06	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0	*	0
CBE-07	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0	*	0
CBE-08	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0	*	0
CBE-08A	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0	*	0
CBE-09	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0	*	0
CBE-10	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0	*	0
CBE-11	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-12	PET/PP	60	0	BASF		WHIT	0.0	*	0
CBE-13	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-14	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-15	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0

COMPOSITE BRAID EVALUATION
YARN B DESCRIPTION

MGS ID#	FIBER B	FIB B DENIER	FIB B FILAM COUNT	FIB B SOURCE	FIB B LOT #	FIB B COLOR	FIB B TWIST LEVEL (TPI)	FIB B TWIST DIRCT (S/Z)	FIB B ENTNG LEVEL
CBE-01	PTFE	75	12	DUPONT	1T153	WHIT	0.0	*	LOW
CBE-02	PTFE	75	12	DUPONT	1T153	WHIT	0.0	*	*
CBE-03	PTFE	75	12	DUPONT	1T153	WHIT	0.0	*	LOW
CBE-04	PTFE	75	12	DUPONT	1T153	WHIT	0.0	*	LOW
CBE-05	PTFE	75	12	DUPONT	1T153	WHIT	0.0	*	LOW
CBE-06	PDS	48	4	SUT DEV	PY001	PURP	0.0	*	0
CBE-07	PDS	48	4	SUT DEV	PY001	PURP	0.0	*	0
CBE-08	PDS	48	8	SUT DEV	PY035	PURP	0.0	*	0
CBE-08A	PDS	48	4	SUT DEV	PY001	PURP	0.0	*	0
CBE-09	PDS	48	4	SUT DEV	PY001	PURP	0.0	*	0
CBE-10	PDS	48	4	SUT DEV	PY001	PURP	0.0	*	0
CBE-11	PP	50	16	SUT DEV	PP005	WHIT	0.0	*	0
CBE-12	*	*	0	*	*	*	0.0	*	0
CBE-13	PP	50	16	SUT DEV	PP005	WHIT	0.0	*	0
CBE-14	PP	50	16	SUT DEV	PP005	WHIT	0.0	*	0
CBE-15	PTFE	110	15	DUPONT	1T138	WHIT	0.0	*	0

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C.A. No.04-12457 PBS
DMI002619

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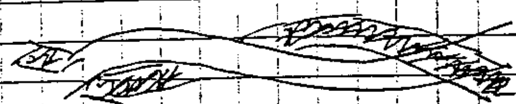
Witness [signature] Date 3-15-90

Page 11
Book No. 2175

Project No. CBE Experiment No. Date
Subject CONTINUED
Purpose

THE YARN BLEND COMPOSITES REQUIRE A PLYING/TWISTING OPERATION BEFORE BRAIDING. PLYING WAS PERFORMED ON THE RATTI 2-FOR-1 TWISTER UTILIZING THE CONDITIONS LISTED IN THE TABLE. PROPER BALANCING OF YARN TENSION WERE REQUIRED TO PREVENT A BARBER POLE APPEARANCE:



PROPER BALANCE OF TENSION

BARBER-POLE APPEARANCE — DUE TO MIS-MATCH IN YARN ELASTIC MODULUS AND TENSION LEVELS

COMPOSITE BRAID EVALUATION
PLIED YARN PROCESS CONDITIONS

MGS ID#	FIBER A	DENIER A	FIBER B	DENIER B	PLY TWIST LEVEL (TPM)	CAN YARN	CREEL YARN	CAN YARN # BRASS DISC WTS	CREEL YARN # GLASS BEADS
CBE-01	PET	70	PTFE	75	0.0	*	*	0	0
CBE-02	PET	70	PTFE	75	3.0	B	A	0	1
CBE-03	PET	70	PTFE	75	0.0	*	*	0	0
CBE-04	PET	70	PTFE	75	0.0	*	*	0	0
CBE-05	PET	70	PTFE	75	0.0	*	*	0	0
CBE-06	VICRYL	28	PDS	48	0.0	*	*	0	0
CBE-07	VICRYL	28	PDS	48	3.0	B	A	0	1
CBE-08	VICRYL	28	PDS	48	0.0			0	0
CBE-08A	VICRYL	28	PDS	48	0.0			0	0
CBE-09	VICRYL	28	PDS	48	0.0	*	*	0	0
CBE-10	VICRYL	28	PDS	48	0.0	*	*	0	0
CBE-11	PET	70	PP	50	0.0			0	0
CBE-12	PET/PP	60	*	*	0.0			0	0
CBE-13	PET	70	PP	50	0.0			0	0
CBE-14	PET	70	PP	50	0.0			0	0
CBE-15	PET	70	PTFE	110	0.0	*	*	0	0

MS 6/6/88

Investigator [signature] Date 6/6/88
Witness Crawford Britt Date 3-15-90

10
Page
Book No.
2175

Project No. MICROFIBER/MMF Experiment No. Date 8/18/88
Subject MONOFILAMENT-/MULTIFILAMENT HYBRID WITH MICROFIBER CORE
Purpose IDEA

IDEA: A IMPROVED SUTURE IS ENVISIONED WHICH COMBINES
THE ATTRIBUTES OF MONOFILAMENTS (EASE OF TISSUE
PASSAGE, NO INFECTION HARBORING INTERSTICES) AND
THE ATTRIBUTES OF MULTIFILAMENT BRAIDS (PLIABILITY,
KNOT STR., KNOT STABILITY, DAMAGE TOLERANCE).
THE HYBRID DESIGN CONSISTS OF POTENTIALLY FOUR
COMPONENTS: 1) MONOFILAMENT-LIKE SHEATH, 2) CORE
MULTIFILAMENT BUNDLE, 3) SHEATH-CORE INTERFACE,
AND 4) MULTIFILAMENT CORE LUBRICANT (OPTIONAL).
MONOFIL. SHEATH IS PREFERABLY FORMED BY EXTRUSION
OR CABLE-WRAPPING/POLISHING. SHEATH POLYMER
CAN BE ABSORBABLE OR NONABSORBABLE, AND SHOULD
BE TOUGH, LOW MODULUS, & POSESS THE PROPER
FRICTIONAL PROPERTIES.

MULTIFILAMENT CORE CONSIST OF A BUNDLE OF
MANY FINE FILAMENTS (1.0 dpf AND FINER) WHICH
MAY BE TWISTED OR BRAIDED. TWISTED STRUCTURES
SHOULD BEHAVE WITH ENHANCED PLIABILITY,
WHEREAS BRAIDED STRUCTURES SHOULD MAINTAIN
ROUNDNESS BETTER.

TWO APPROACHES ARE POSSIBLE REGARDING THE
SHEATH-CORE INTERFACE. ONE IS TO MAXIMIZE
ADHESION TO PREVENT TEARING/STRIPPING. IT
IS BELIEVED THAT THIS WILL DETRACT FROM PLIABILITY
BY INHIBITING YARN/FIBER MOBILITY. THE
OTHER APPROACH IS TO MINIMIZE SHEATH-CORE
ADHESION, POSSIBLY BY THE INCORPORATION OF
AN OIL LIKE LUBRICANT (SILICONE OIL FOR EXAMPLE)
OR SOLID LUBRICANT LIKE PTFE FIBERS IN THE
CORE BUNDLE. THIS SAME LUBRICATION APPROACH MAY
BE OF VALUE WITHIN THE CORE BUNDLE TO
MINIMIZE FIBER-FIBER INTERACTIONS.

THE RESULTING SUTURE SHOULD HAVE EXC. TISSUE PASSAGE, PLIABILITY,
KNOT PROPS, RESISTANCE TO CATASTROPHIC DAMAGE AND MINIMAL
TENDENCY FOR INFECTION HARBOURING.

Investigator [signature] Date 8/18/88
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10
Page
Book No.
2175

Date 9/27/88

Project No. STS Experiment No.
Subject TRIBOHESION PROCESSED STS BRAID SAMPLES
Purpose SEM + PHYS. PROP CHARACTERIZATION

BACKGROUND: 23 SAMPLES OF TRIBOHESION (LONDON, UK) PROCESSED BRAID SAMPLES WERE SUPPLIED BY MR E. NAGY IN OUR MEETING AT ETHICON ON 7/26/88. THE STRANDS WERE COMPRISED OF 2-0 STS PTFE BRAID WHICH WAS CABLE WRAPPED AND POLISHED. STRAND LENGTH WAS 1-2 m. LIMITED INFORMATION WAS RELEASED BY TRIBOHESION ON THE PROCESSING OF THE SAMPLES, BUT IT IS KNOWN THAT THE PROCESS VARIABLES INCLUDE LINE SPEED, TAPE TENSION, TAPE WIDTH + THICKNESS, AND DEGREE OF POLISHING.

RESULTS: PHYSICAL PROPERTY CHARACTERIZATION VS. ORIGINAL STS BRAID AND GORE-TEX:

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PHYSICAL PROPERTY CHARACTERIZATION

PROPERTY	UNITS	ORIGINAL 2-0 STS BRAID	TRIBOHESION PROCESSED 2-0 STS BRAID #13	GORE-TEX SIZE 4-0 MONOFILAM.
DIAMETER USP	(MILS)	12.1	20.2	13.6
OPTICAL	(MILS)	N/A	26.5	N/A
STR. TENSILE	(LBS)	4.1	7.8	5.0
INTRIN. TENSILE (USP DIAM)	(PSI)	35,600	24,300	34,400
ULT. ELONGATION	(%)	20.0	55.1	25.5
KNOT STRENGTH	(LBS)	3.9	7.1	4.1
INTRIN. KNOT	(PSI)	33,900	22,100	28,200
KNOT/STRAIGHT STR	(%)	95	91	82
KNOT SECURITY*	(# OF THROWS)	6	5-6	6-7

N/A : not available * : composite of several lots and sizes

MS 9/27/88

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C.A. No.04-12457 PBS
DMI002622

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Page
Book No.
2175

Project No. Experiment No. Date 9/27/88
Subject TRIBOHESION
Purpose CONTINUED

SEM OBSERVATIONS:

1) SAMPLES WITH POOR SUBJECTIVE SMOOTHNESS POSSESSED AN OVERSIZED SHEATH WHICH DISTORTED EASILY. DISTORTION WAS EITHER A WRINKLING DUE TO TORSION OR AN BELLOWS TYPE FOLDING DUE TO SHEATH SLIDING.

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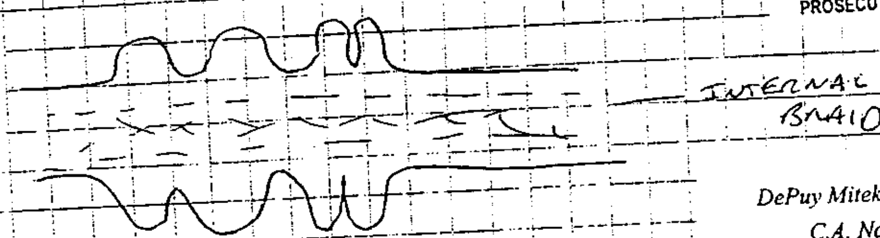

BELLOWS TYPE SHEATH FOLDING

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C.A. No.04-12457 PBS
DMI002623

2) SAMPLES WITH GOOD SUBJECTIVE SMOOTHNESS APPEARED MONOFIL. LIKE AT 55X.

3) TAPE SEAMS WERE VISABLE IN NON-POLISHED SAMPLES AT 55X.

4) SIGNIFICANT SHEATH DISTORTION OBSERVED AROUND KNOT, BUT NO SHEATH TEARING.

5) THE MICROSTRUCTURE OF THE SHEATH FILM IS EXPANDED LIKE THE GORE PRODUCT, BUT THE TRIBOH. PRODUCT IS TO A LESSER DEGREE (550X)

6) SHEATH DISTORTION WAS EXCESSIVE IN REGIONS OF HIGH PICK DENSITY.

DISCUSSION
- PHYS PROPS ARE LOW ESPECIALLY SINCE SHEATH INCR DIAM
- PET OR PET/PTFE GORE BRAID SHOULD BE EXPLORED
- OVERSIZED SHEATHS DISTORT AND BECOME 'ROUGH'

Investigator [signature] Date 9/27/88
Witness [signature] Date 2-15-90

Page ..... Book No. .....

2175

Project No. MMH Experiment No. .... Date 10/19/88

Subject MONOFILAMENT - MULTIFILAM. HYBRID

Purpose IDEA

IDEA - FOLLOW UP FROM 2175 - 12.

THE ADDITION OF A SILICONE TYPE OIL TO THE TWISTED OR BRAIDED CORE BUNDLE CAN DRAMATICALLY IMPROVE PLIABILITY. HOWEVER, IT COULD ALSO INHIBIT WICKING OF BIOLOGICAL FLUID INTO THE FILAMENT CORE WHICH MIGHT OTHERWISE LEAD TO INFECTION. THIS HAS BEEN A PROBLEM WITH PREVIOUS APPROACHES OF THIS NATURE. THE LUBRICANT SHOULD BE HYDROPHOBIC (LOW SURFACE TENSION) AND COULD BE ABSORBABLE OR NONABSORBABLE. ALSO, FINE DPF FILAMENTS WOULD ALSO INHIBIT WICKING BY RESULTING IN A SMALLER DIAM. SIZE.

IF THE MONOFIL. SHEATH IS EXTRUDED, IT MAY BE BENEFICIAL TO FORM IT WITH AN ANNULAR DIE TO MINIMIZE THE PENETRATION OF THE MOLTEN SHEATH POLYMER INTO THE CORE BUNDLE. OTHER PRECAUTIONS TO MINIMIZE SHEATH-CORE ADHESION INCLUDE RAPID SHEATH QUENCHING + DRAWING/ORIENTATION.

IN THE CASE OF ABSORBABLE HYBRIDS, LOW MW ANALOGS OF PDD, CAPROLACTONE, PGA, PLA AS DESCRIBED BY AL HUNTER MAY BE USEFUL AS THE LUBRICANTS.

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Witness Crawford Britt Date 3-15-90

Page 175
Book No.

Project No. CBE Experiment No. Date 11/11/88
Subject COMPOSITE BRAID EVALUATION
Purpose PROCESS CONDITIONS AND PROPS

BACKGROUND: CONTINUATION OF 2175-8, 14 COMPOSITE BRAIDS WERE PROCESSED AND CHARACTERIZED - (CONSTRUCTIONS AND YARN LOT INFO ON PGS 8-11). BRAID PROCESS CONDITIONS WERE AS FOLLOWS:

COMPOSITE BRAID EVALUATION
BRAID PROCESS CONDITIONS

MGS ID#	BRAIDER NO.	GEAR NO.	RPM	SHEATH SPRING DIAM. (MILS)	SHEATH SPRING LENGTH (IN)	CORE TENSION TYPE	CORE TXTRL SET PT	GLASS ROD	CORE TENSION MEAS. (GMS)
CBE-01	6	32	183	0.009	5.0	TXTRL	1.0	Y	18
CBE-02	6	32	183	0.009	5.0	TXTRL	1.5	Y	20
CBE-03	*	*	*	0.000	0.0	*	0.0	*	0
CBE-04	6	32	183	0.009	5.0	TXTRL	1.0	Y	21
CBE-05	3	36	170	0.000	0.0	TXTRL	1.0	Y	22
CBE-06	12	32	182	0.009	5.0	TXTRL	1.0	Y	20
CBE-07	12	32	182	0.009	5.0	TXTRL	1.0	Y	17
CBE-08	*	*	*	0.000	0.0		0.0		0
CBE-08A				0.000	0.0		0.0		0
CBE-09	12	32	182	0.009	5.0	TXTRL	1.0	Y	17
CBE-10	12	32	182	0.009	5.0	TXTRL	1.0	Y	19
CBE-11				0.000	0.0		0.0		0
CBE-12				0.000	0.0		0.0		0
CBE-13	10	32	183	0.009	5.0	TXTRL	1.0	Y	18
CBE-14	12	36	182	0.009	5.0	TXTRL	1.0	Y	17

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KEY:
TXTRL: TEXTROL TENSION DEVICE

THE PET/PTFE SAMPLES (CBE-01 TO 05) HAD A RANGE OF PROCESSING PROBLEMS ~~AS~~ SUCH AS CORE-POPPING AND LOOSENESS. CBE-03 WAS ABANDONED SINCE THE PTFE YARN WAS INTERLACED MAKING COMMINGLING IMPOSSIBLE. CBE-01 HAD SPRINGS ONLY ON PET CARRIERS, NO SPRINGS ON PTFE CARRIERS. CBE-08 (VIC/ROS) WAS ABANDONED SINCE COMMINGLING WAS IMPOSSIBLE. CBE-12 WAS DELAYED DUE TO SOURCING PROBLEMS WITH THE BICOMPONENT FIBER.

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Page
Book No.
2175

Project No. CBE Experiment No. Date 11/1/88
Subject CONTINUED
Purpose

FOLLOWING BRAID PROCESSING, THE MATERIALS WERE HOT-STRETCHED ACCORDING TO THE FOLLOWING CONDITIONS:

HOT STRETCH CONDITIONS

MGS ID#	HOT-STRETCH %	ROLL 1 FPM	ROLL 2 FPM	ROLL 1 # OF WRAPS	ROLL 2 # OF WRAPS	ZONE 1 TEMP (C)	ZONE 2 TEMP (C)	ZONE 3 TEMP (C)	ZONE 4 TEMP (C)
CBE-01	30	9.0	11.7	8	12	125	150	190	225
CBE-02	30	9.0	11.7	8	12	125	150	190	225
CBE-03	0	0.0	0.0	0	0	0	0	0	0
CBE-04	30	9.0	11.7	8	12	125	150	190	225
CBE-05	30	9.0	11.7	8	12	125	150	190	225
CBE-06	10	9.0	9.8	8	12	125	150	190	215
CBE-07	10	9.0	9.8	8	12	125	150	190	215
CBE-08	0	0.0	0.0	0	0	0	0	0	0
CBE-08A	0	0.0	0.0	0	0	0	0	0	0
CBE-09	10	9.0	9.8	8	12	125	150	190	215
CBE-10	10	9.0	9.8	8	12	125	150	190	215

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INITIAL PHYSICAL PROPERTY CHARACTERIZATION YIELDED THE FOLLOWING RESULTS:

PHYSICAL PROPERTY CHARACT

MGS ID#	USP DIAN (MILS)	ULTIMAT TENSILE STREN (LBS)	INTRIN TENSILE STREN (PSI)	ULTIMAT KNOT STREN (LBS)	INTRIN KNOT STREN (PSI)	KNOT CONVER (%)	ULTIMAT ELONGAT (%)	STRAND BENDING RIGIDITY (GMxCM2)	KNOT STABIL (# THROWS)	PICKS PER INCH	TOTAL DENIER
CBE-01	0.0	0.00	0	0.00	0	0	0	0.00			
CBE-02	0.0	0.00	0	0.00	0	0	0	0.00			
CBE-03	0.0	0.00	0	0.00	0	0	0	0.00	0		
CBE-04	0.0	0.00	0	0.00	0	0	0	0.00			
CBE-05	0.0	0.00	0	0.00	0	0	0	0.00			
CBE-06	10.7	6.79	75450	4.37	48580	64	29	0.00	*	46	1058
CBE-07	13.9	10.16	66930	6.46	42808	64	28	0.00	*	45	1019
CBE-08	0.0	0.00	0	0.00	0	0	0	0.00			
CBE-08A	0.0	0.00	0	0.00	0	0	0	0.00			
CBE-09	14.1	15.70	100540	7.98	51490	51	29	0.00	*	44	1099
CBE-10	10.9	7.00	75030	4.47	47650	64	42	0.00	*	51	612

MS

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C.A. No.04-12457 PBS
DMI002626

THE PROPERTIES OF THE COMPOSITES ARE AS EXPECTED MIDWAY BETWEEN THE CONTROLS.

Investigator Mark Steckel Date 11/1/88
Witness Crawford Britt Date 3-15-90

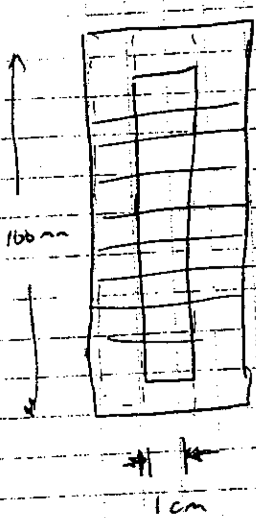
Page 18
Book No. 2175

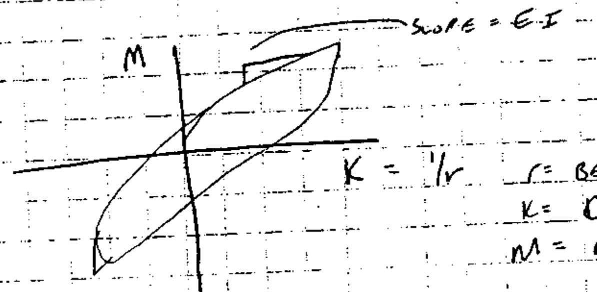
Project No. KAWABATA Experiment No. ______ Date 11/15/88
Subject KAWABATA - BENDING RIGIDITY TESTING
Purpose INITIAL RESULTS OF BENDING TESTING

BACKGROUND: THE KAWABATA BENDING RIGIDITY TESTER AT PHILA. COLLEGE OF TEXTILES + SCIENCE WAS UTILIZED TO MEASURE THE PLIABILITY OF BRAIDED SUTURES.

PROCEDURE:

AN ARRAY OF PARALLEL STRANDS OF BRAIDED SUTURES WERE MOUNTED BETWEEN TWO CARDBOARD TABS AS SHOWN BELOW. TYPICALLY 40 ENDS WERE USED ALTHOUGH THIS VARIES WITH THE SUTURE SIZE. THE KAWABATA TESTER MEASURES THE TORQUE AS A FUNCTION OF BENDING CURVATURE OF THE PARALLEL SUTURES. THE BENDING RIGIDITY





r = BENDING RADIUS
K = CURVATURE
M = BENDING MOMENT

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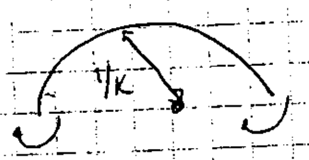

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002627

IS THE SLOPE OF THE BENDING MOMENT — CURVATURE TRACES. THE FOLLOWING VALUES WERE OBTAINED ON OFF-BRAIDER + HOT-STRET. POLYESTER:

BENDING RIGIDITY (GM·CM²/STRAND)	SIZE →	6-0	4-0	2-0	0	2
	OFF-BRAIDER	.004	0.026	0.029	0.036	.087
	HOT-STRETCHED	.002	0.024	0.253	0.103	0.267

AS EXPECTED, THE EI GENERALLY INCR. AS SIZE INCREASES, AND ALSO INCR. W/ HOT-STRETCHING.

Investigator [signature] Date 11/15/88
Witness [signature] Date 2-15-90

2175

Project No. BCAD Experiment No. Date 11/18/88
Subject BRAID CAD - MODEL CONSTRUCTIONS
Purpose DEFINE MODEL CONSTRUCTIONS

BACKGROUND: THE JOINT DEVELOPMENT PROGRAM BETWEEN ETHICON + DREXEL UNIV IS TO DEFINE SOFTWARE TO DESIGN BRAIDED SUTURES. EXPERIMENTAL DATA IS REQUIRED ON SIMPLE, WELL-BEHAVED BRAIDED GEOMETRIES IN ORDER TO CONFIRM THE THEORETICAL PREDICTIONS. THE FOLLOWING CONSTRUCTIONS HAVE BEEN CHOSEN FOR DUPONT DACRON PET TYPE 52:

CARRIERS	CORE	PICK GEARS		
3	0	22	26	30
4	0	26	30	34
8	0	28	32	36
8	1	28	34	36
12	2	28	32	36
16	3	26	30	34

THE ABOVE CONSTRUCTIONS ARE TO BE MADE WITH YARN WITH PRODUCER'S TWIST. TO EVALUATE THE EFFECT OF TWIST, A SMALLER SET OF SAMPLES HAS BEEN DESIGNED:

CARRIERS	CORE	PICK GEAR	TWIST LEVELS
8	1	34	0, 1.5, 3, 6

TENSILE, DIAMETER, SURFACE PROPS, BENDING RIGIDITY CHARACTERIZATION WILL BE PERFORMED ON ALL ABOVE BRAIDS.

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Page

Book No. 175

Project No. DuPont Experiment No. Date 12/7/88

Subject DuPont Hollow + Multilobal Fiber Evaluation

Purpose Evaluate Experimental Materials

BACKGROUND: Two experimental Dacron PET yarns were provided by DuPont for evaluation as suture yarns. Yarn descriptions are given in Table 1: (1) Multilobal (4) Hollow

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C.A. No.04-12457 PBS
DMI002629

TABLE 1.

Exploratory Dupont Yarn

1. Dacron 50 den 34-R14
   Textile Yarn Rotoset
   Semidull Type 929 Tube
   Reference 7184 Merge 12601

2. Nylon 30 den 10-R25
   Textile Yarn Rotoset
   Dead Bright Type 335
   Reference 40244 Merge 18681

3. Nylon 70 den -66-R25-295-M
   Merge 64402

4. Polyester Hollow Multifilament Yarn
   Round Semi-dull
   71.6 den 50 filaments
   Void size : 13.8%
   Tenacity: 5.0 gpd Modulus: 90.4 gpd Elong.: 16.0%
   Finish 0.65-1.00%

MS

PROCESS CONDITIONS

DUPONT HOLLOW AND MULTILOBAL FIBER BRAIDS

THE YARNS WERE PROCESSED INTO BRAIDS ACCORDING TO MERSILENE PROCESS SPECS FOR SIMILAR DEN YARN. THE BRAIDS WERE SCOURED + HOT-STRETCHED TO MERSILENE SPECS (SEE TABLE →)

PARAMETER	DFE-1	DFE-2
Fiber Type	Multilobal	Hollow
Denier/Filaments	50/34	72/50
Construction	16x3	12x1
Pick gear	30	12
RPM	174	174
Sheath springs	none	0.009x5"
Core tension set	1.0	1.0
Hot str %	15	15
H S Temp (F)	225	225

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Witness [signature] Date 3-15-90

21
Page
Book No.
2175

Project No. DuPont Experiment No. Date 12/7/88
Subject Continued
Purpose

RESULTS:
THE HOT-STRETCHED BRAIDS WERE CHARACTERIZED ACCORDING TO STANDARD PHYS. PROP. TESTING AND ARE COMPARED TO STANDARD MERSILENE HOT-STR. BRAIDS:

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SUTURE PHYSICAL PROPERTIES

STANDARD AND SPECIALTY DACRON PET FIBER BRAIDS

MATERIAL DESCRIP.	DIAM (DIAM)	TENSL. STREN. (LBS)	INTRIN. TENSL. STREN. (KSI)	ELONG. (%)	KNOT STREN. (LBS)	INTRIN. KNOT STREN. (KSI)
DFE-1 MULTI-LOBAL PET 50-34-R14 SIZE 2-0	12.8	6.4	49.4	40.5	5.2	40.5
MERSILENE SIZE 2-0 GREEN	12.7	14.2	112.1	11.0	7.1	56.1
DFE-2 HOLLOW PET 72-50 SIZE 0	14.4	10.7	65.7	28.3	7.2	44.1
MERSILENE SIZE 0 GREEN	15.0	15.2	87.7	16.0	8.9	50.4

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C.A. No.04-12457 PBS
DMI002630

DISCUSSION:
THESE YARN TYPES APPEAR TO OFFER NO SIGNIF. IMPROVEMENTS IN SUTURE PROPS. STRAIGHT + KNOT TENSILES ARE SUBSTANTIALLY LOWER IN BOTH CASES. KNOT CONVERSION IS RELATIVELY GOOD FOR MULTILOBAL (82% VS 50% FOR THE 2-0 CONTROL), HOWEVER IT IS NOT CLEAR WHETHER THIS IS DUE TO X-SECT SHAPE OR LOWER MOD. YARN.

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Witness Crawford Britt Date 3-15-90

Page 20
Book No. 175

Project No. PDS Experiment No. ________ Date 12/14/88

Subject PDS BRAIDS - 2 + 12 DPF EVALUATION

Purpose EVALUATE BIOLOGICAL + PHYSICAL PROPERTIES

PROCEDURE: PDS MULTIFILAMENT YARNS WERE BRAIDED AND EVALUATED FOR BIOLOGICAL PROPERTIES ~~AND~~ (IN VITRO AND INVIVO). THE YARN WAS OBTAINED FROM DR. E. BROYER AND POSSESSED THE FOLLOWING PROPS:

Properties of PDS* Yarns

sample	denier	dpf	tenacity g/den	elong. %
RLS-248E	58.7	11.74	6.75	63
QPY-022-3-2	74.9	14.98	4.8	21
QPY-023-5-1	67.3	13.46	5.6	21
PY-045	57.8	2.06	5.25	59.95

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ALL YARN WAS BRAIDED PER VICRYL 2-0 SPECIFICATION THE FOLLOWING COMPARES THE INVIVO AND INVITRO DATA VS. PDS MONOFILAMENT AND VICRYL BRAID:

PDS BRAID IN VITRO PERFORMANCE

BRAID ID	FIBER DPF	YARN ID	BRAID SIZE	BASELINE TENSILE (PSI)	IN VITRO 5 DAY % BSR	PDS MONOFIL TENSILE (PSI)	PDS MONOFIL IN VITRO 5D %BSR	VICRYL BRAID TENSILE (PSI)	VICRYL BRAID IN VITRO 12D %BSR	INVIVO 21 DAY % BSR
CBS-001	2.1	PY-045	2-0	70930	23.6	87490	64.2	112300	54.8	3
CBS-002	15.0	QPY-022	2-0	57300	34.9	87490	64.2	112300	54.8	22
CBS-003	11.7	RLS-248E	2-0	70270	47.1	87490	64.2	112300	54.8	26
CBS-004	13.5	QPY-023	3-0	61350	48.7	95440	82.1	120150	56.2	36

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C.A. No.04-12457 PBS
DMI002631

DISCUSSION:
THE 2 DPF PRODUCT HAS EXCEPTIONALLY POOR BSR - 3% AT 21 DAY VS APPROX 56% FOR VICRYL 2-0. THE ≈12 DPF PRODUCT WERE SIGNIFICANTLY BETTER BUT STILL INFERIOR TO VICRYL OR PDS MONOFIL. THE HAND OF THE PRODUCT WAS ALSO INFERIOR TO VICRYL FROM A STIFFNESS VIEWPOINT. THE 2-0 DPF POSSESSED A HIGH # OF BROKEN FILAMENTS WHICH CONTRIBUTED TO BRAID ROUGHNESS.

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Witness [signature] Date 3-15-90

Page ......

Book No. ......

Project No. IFI Experiment No. .... Date 12/14/88

2175

Subject BRAID PROCESS CONDITIONS, H.S. CONDITIONS, PHYS PROP CHARACT.

Purpose CHARACTERIZATION OF COMPOSITE IFI BRAIDS

CONTINUATION FROM PG. 6:

BACKGROUND: ROOT AND RMS VICRYL/PDS + PET/PP BRAID CONSTRUCTIONS HAVE BEEN DEFINED PREVIOUSLY. BRAIDS WERE PROCESSED ACCORDING TO FOLLOWING CONDITIONS:

IFI BRAID PROCESS CONDITIONS

IFI #	LAB ID #	SIZE	TYPE	FIBER 1	FIBER 2	PICK GEAR #	SHEATH SPRING DIAM. x LENGTH	CORE TENS TYPE	CORE TENS SET	CORE TENS MEAS (GMS)	BRAIDER RPM	PLY TWIST (TPI)
1	SBZ-020	4-0	ROOT	VIC	PDS	27	NONE	TXTL	0.0	12	160	*
2	SBZ-007	4-0	ROOT	VIC	PDS	20	NONE	BUTT	NONE		180	*
3	SBZ-009	4-0	ROOT	PET	PP	29	NONE	NONE	*	*	180	*
4	SBZ-005	3-0	ROOT	VIC	PDS	30	9x5.0	NONE	*	*	160	*
5	SBZ-006	3-0	ROOT	VIC	PDS	30	9x5.0	NONE	*		180	*
6	SBX-010	3-0	ROOT	PET	PP	30	9x5.0	BUTT	9x5.0		183	*
7	SBZ-023	3-0	RMF	PET	PP	31	9x5.0	TXTL			160	3.0
8	SBZ-022	3-0	RMF	PET	PP	30	9x5.0	TXTL	0	20	182	3.0
9	SBZ-021	3-0	RMF	VIC	PDS	27	9x5.0	TXTL		12	182	3.0
10	SBZ-025	3-0	RMF	PET	PP	31	NONE	TXTL		35	160	3.0
11	SBZ-024	3-0	RMF	VIC	PDS	31	9x5.0	TXTL			183	3.0
12	SBZ-028	3-0	RMF	VIC	PDS	--	--	----	----	---	0	---
13	SBZ-027	3-0	RMF	PET	PP	31	NONE	TXTL		26	160	3.0
14	*	3-0	RMF	VIC	PDS	*	*	*	*	*	0	*
15	SBZ-013	4-0	ROOT	PET	PP	27	NONE	BUTT		80	182	3.0

MH

CORE POPPING WAS A CONSIDERABLE PROBLEM IN NEARLY ALL BRAIDS DUE TO MISMATCH'S IN ELASTIC MODULI.

ALL MATERIALS WOUND ON HALOBA AND BRAIDED ON N.E. BUTTS. TEXTROL TENSION CONTROL UNITS WERE USED ON CORE YARNS.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002632

Investigator [signature] Date 12/14/88

Witness Crawford Britt Date 3-15-90

Page
Book No.
175

Project No. IFI Experiment No. Date 12/14/88
Subject
Purpose CONTINUED

AFTER BRAIDING AND APPROPRIATE SCOURING (ETAC FOR VIC/PDS, AQUEOUS DETERGENT FOR PP/PET), THE BRAIDS WERE HOT-STRETCHED IN A FORCED CONVECTION TUNNEL AT THE FOLLOWING CONDITIONS:

IFI BRAID HOT-STRETCH CONDITIONS

IFI #	LAB ID#	FIBER 1	FIBER 2	HOT-STRET PERCN (%)	GODET 1 FPM	GODET 1 # WRPS	GODET 2 # WRPS	ZONE 1 TEMP (F)	ZONE 2 TEMP (F)	ZONE 3 TEMP (F)	ZONE 4 TEMP (F)
1	SBZ-020	VIC	PDS	*	0.0	0	0.0	0	0	0	0
2	SBZ-007	VIC	PDS	22	9.0	9	11.0	125	150	175	195
3	SBZ-009	PET	PP	35	7.0	7	10.7	122	146	170	194
4	SBZ-005	VIC	PDS	11	9.0	7	10.0	122	146	170	194
5	SBZ-006	VIC	PDS	22	9.0	7	11.0	125	150	175	195
6	SBX-010	PET	PP	34	8.0	7	10.7	175	225	250	300
7	SBZ-023	PET	PP	34	8.0	8	10.7	175	225	250	300
8	SBZ-022	PET	PP	34	8.0	7	10.7	175	225	250	295
9	SBZ-021	VIC	PDS	10	10.0	7.	11.0	125	150	175	195
10	SBZ-025	PET	PP	34	8.0	7	10.7	175	225	250	295
11	SBZ-024	VIC	PDS	34	8.0	9	10.0	125	150	175	195
12	SBZ-028	VIC	PDS	--	0.0	0	0.0	0	0	0	0
13	SBZ-027	PET	PP	--	0.0	0	0.0	0	0	0	0
14	*	VIC	PDS	*	0.0	0	0.0	0	0	0	0
15	SBZ-013	PET	PP	34	8.0	7	10.7	175	225	250	300

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A HIGHER THAN PREFERRED HOT-STRETCH RATIO WAS SOMETIMES REQUIRED IN ORDER TO REMOVE THE WIDE-SPREAD BONE-POPS.

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C.A. No.04-12457 PBS
DMI002633

Investigator [signature] Date 12/14/88
Witness Crawford Britt Date 3-15-90

Page ....
Book No. ....
2175

Project No. IFI Experiment No. .... Date 12/14/88

Subject CONT.

Purpose ....

THE FOLLOWING ARE THE PHYSICAL PROPERTIES OF ~~THE BRAIDS~~ THE IFI BRAIDS:

IFI BRAID COMPOSITES
TEST RESULTS

IFI #	TYPE	FIBER 1	FIBER 2	SIZE	DIAM (MILS)	STD. DEV.	TENSL (LBS)	STD. DEV.	INTRIN TENSL (PSI)	KNOT TENSL (LBS)	STD. DEV.	INTRIN KNOT TENSL (PSI)	ELONG (%)	STD. DEV.
2	ROOT	VIC	PDS	4-0	8.9	0.1	5.5	0.2	87.8	3.6	0.3	57.7	25.7	1.3
3	ROOT	PET	PP	4-0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
4	ROOT	VIC	PDS	3-0	10.3	0.0	7.8	0.4	93.7	4.8	0.2	57.9	29.2	2.2
5	ROOT	VIC	PDS	3-0	10.4	0.2	6.6	0.1	0.0	4.2	0.5	0.0	16.9	1.2
6	ROOT	PET	PP	3-0	10.9	0.0	6.1	0.2	65.8	4.4	0.2	47.5	28.2	3.1
7	RMF	PET	PP	3-0	11.6	0.2	6.7	0.1	0.0	4.7	0.2	0.0	31.8	1.5
8	RMF	PET	PP	3-0	12.9	0.1	7.9	0.1	0.0	5.4	0.2	0.0	24.1	1.0
9	RMF	VIC	PDS	3-0	11.0	0.1	8.3	0.2	0.0	4.4	0.2	0.0	34.0	1.6
10	RMF	PET	PP	3-0	12.7	0.1	7.5	0.1	0.0	5.0	0.3	0.0	22.4	0.7
11	RMF	VIC	PDS	3-0	10.5	0.2	7.5	0.1	0.0	5.0	0.3	0.0	21.0	0.6
12	RMF	VIC	PDS	3-0	12.6	0.1	11.2	0.2	0.0	6.4	0.2	0.0	28.2	1.2
13	RMF	PET	PP	3-0	7.8	0.1	4.1	0.1	0.0	2.6	0.1	0.0	12.4	1.2
14	RMF	VIC	PDS	3-0	******	****	*****	****	******	*****	****	******	*****	****
15	ROOT	PET	PP	4-0	10.2	0.1	7.8	0.4	93.7	4.3	0.2	52.8	29.2	2.2
1	ROOT	VIC	PDS	4-0	7.9	0.1	4.5	0.2	92.3	2.8	0.1	58.2	29.3	2.0

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APPROXIMATELY 750 YDS OF EACH BRAID WAS DELIVERED TO DR E. BROYER FOR FURTHER PROCESSING

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C.A. No.04-12457 PBS
DMI002634

Investigator [signature] Date 12/14/88

Witness Crawford Britt Date 3-15-90

Page
Book No.
175

Project No. CBE Experiment No. Date 2/2/89
Subject PET/PTFE COMPOSITE BRAIDS
Purpose EXPLORATORY EVALUATION OF VARIOUS PROCESS METHODOLOGIES

BACKGROUND - PAGE 8

ADDITIONAL PET/PTFE COMPOSITES BRAIDS WERE PRODUCED UTILIZING 1) CARRIER BLEND, 2) YARN BLEND, 3) COMMINGLING TECHNOLOGIES. CONTROLS OF 100% PET AND 100% PTFE WERE ALSO PRODUCED. FIBER SUPPLY/TYPE/DENIER, BRAID CONSTRUCTION, SCOUR CONDITION, H.S. CONDITIONS WERE CONSTANT FOR ALL BRAIDS.

THE FOLLOWING IS THE YARN INFORMATION/DESCRIPTION:

COMPOSITE BRAID EVALUATION
YARN A DESCRIPTION

MGS ID#	FIBER A	FIB A DENIER	FIB A FILAM COUNT	FIB A SOURCE	FIB A LOT #	FIB A COLOR	FIB A TWIST LEVEL (TPI)	FIB A TWIST DIRCT (S/Z)	FIB A ENTANG LEVEL
CBE-15	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-16	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-16A	PET	70	34	DUPONT		WHIT	0.0	*	R14
CBE-17	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-18	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-19	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0

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COMPOSITE BRAID EVALUATION
YARN B DESCRIPTION

MGS ID#	FIBER B	FIB B DENIER	FIB B FILAM COUNT	FIB B SOURCE	FIB B LOT #	FIB B COLOR	FIB B TWIST LEVEL (TPI)	FIB B TWIST DIRCT (S/Z)	FIB B ENTNG LEVEL
CBE-15	PTFE	110	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-16	PTFE	110	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-16A	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-17	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-18	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-19	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002635

Investigator [signature] Date 2/2/89
Witness Raymond Britt Date 3-15-90

Page 61
Book No.
2175

Project No. CBE Experiment No. Date 2/2/89

Subject PET/PTFE COMPOSITES

Purpose CONTIN.

APPROX. 50/50 BY VOLUME BRAIDS WERE PRODUCED IN THE FOLLOWING CONSTRUCTION + CONDITIONS:

COMPOSITE BRAID EVALUATION
BRAID CONSTRUCTIONS

MS

MGS ID#	COMP TYPE	BRAID TYPE	SIZE	SHxCR CARR.	FIBER A	DEN A	FIBER A VOLUM FRACT	FIBER B	DEN B	FIBER B VOLUM FRACT	SH CARR FIB A	SH CARR FIB B	SH CARR FIB C	CR CARR FIB A	CR CA FIB
CBE-15	CB	CS	1	12x1	PET	70	51	PTFE	110	49	DIAGRM	DIAGRM	*	1	1
CBE-16	YB	CS	1	12x1	PET	70	51	PTFE	110	49	1-12	1-12	*	1	1
CBE-16A	YB	CS	1	12x1	PET	70	51	PTFE	115	49	1-12	1-12	*	1	1
CBE-17	CF	CS	1	12x1	PET	70	51	PTFE	115	49	1-12	1-12	*	1	1
CBE-18	CT	CS	1	12x1	PET	70	100	PTFE	115	*	1-12	*	*	1	*
CBE-19	CT	CS	2	12x1	PET	70	*	PTFE	115	100	*	1-12	*	*	1

MS

COMPOSITE BRAID EVALUATION
BRAID PROCESS CONDITIONS

MGS ID#	BRAIDER NO.	GEAR NO.	RPM	SHEATH SPRING DIAM. (MILS)	SHEATH SPRING LENGTH (IN)	CORE TENSION TYPE	CORE TXTRL SET PT	GLASS ROD	CORE TENSION MEAS. (GMS)
CBE-15	12	30	182	0.009	5.0	TXTRL	1.0	Y	16
CBE-16	00	31	215	0.009	5.0	TXTRL	1.0	Y	16
CBE-16A	00	36	215	0.009	5.0	TXTRL	1.0	Y	20
CBE-17	12	32	182	0.009	5.0	TXTRL	0.0	Y	14
CBE-18	12	30	182	0.009	5.0	TXTRL	1.0	Y	17
CBE-19	12	36	182	0.009	5.0	TXTRL	1.0	Y	15

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002636

Investigator [signature] Date 2/2/89
Witness Crawford Britt Date 3-15-90

Page ....
Book No. 2175

Project No. CBE Experiment No. .... Date 2/2/89

Subject PET/PTFE Composites

Purpose Continued

The above braids were scoured in skein form in a beaker w/ an aqueous detergent system. Following scouring + dry, the braids were hot-stretched as follows:

COMPOSITE BRAID EVALUATION
HOT STRETCH CONDITIONS

MGS ID#	HOT-STRETCH %	ROLL 1 FPM	ROLL 2 FPM	ROLL 1 # OF WRAPS	ROLL 2 # OF WRAPS	ZONE 1 TEMP (C)	ZONE 2 TEMP (C)	ZONE 3 TEMP (C)	ZONE 4 TEMP (C)
CBE-15	30	9.0	11.7	8	12	125	150	190	225
CBE-16	30	9.0	11.7	8	12	125	150	190	225
CBE-16A	30	9.0	11.7	8	12	125	150	190	225
CBE-17	30	9.0	11.7	8	12	125	150	190	225
CBE-18	30	9.0	11.7	8	12	125	150	190	225
CBE-19	30	9.0	11.7	8	12	125	150	190	225

The hot-stretched braids were characterized per standard suture test methods:

COMPOSITE BRAID EVALUATION

PHYSICAL PROPERTY CHARACTERIZATION

MGS ID#	USP DIAN (MILS)	ULTIMAT TENSILE STREN (LBS)	INTRIN TENSILE STREN (PSI)	ULTIMAT KNOT STREN (LBS)	INTRIN KNOT STREN (PSI)	KNOT CONVER (%)	ULTIMAT ELONGAT (%)	STRAND BENDING RIGIDITY (GMxCM2)	KNOT STABIL (# THROWS)	BSR CONTL (LBS)	BSR 21 DAY (LBS)	BSR 21 DAY (%)	PICKS PER INCH	TOTAL DENIER
CBE-15	18.6	14.14	51758	9.64	35254	68	34	2.24E-2	5	0.00	0.00		44	2529
CBE-16	19.1	13.07	45460	9.52	33116	73	30	2.20E-2	5	0.00	0.00		45	2694
CBE-16A	0.0	0.00	0	0.00	0	0	0	0.00		0.00	0.00		41	2565
CBE-17	19.9	13.88	44850	11.02	35600	79	39	1.28E-2	5	0.00	0.00			
CBE-18	19.5	21.30	71295	13.54	45241	63	27	3.00E-2	4	0.00	0.00			
CBE-19	20.6	7.37	21460	5.96	17763	79	57	1.12E-2	7	0.00	0.00		39	2970

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002637

Page ....
Book No. ....

Project No. CBE Experiment No. .... Date 2/2/89 2175

Subject PET/PTFE COMPOSITES

Purpose CONTINUED :

1) DISCUSSION:

FROM A BRAID PROCESSING VIEWPOINT, THE COMMINGLED YARN WAS THE LEAST PROBLEMATIC BRAID FOLLOWED BY THE YARN BLEND. THE CARRIER BLEND PRESENTED THE MOST DIFFICULTIES IN CONE COPPING AND BRAID LOOSENESS. THE COMMINGLED YARN DID POSSESS REGIONS WHERE THE YARNS SEPARATED RESULTING IN BRAIDING DIFFICULTY AND ROUGHNESS.

FROM A PROPERTY VIEWPOINT, THE INTRINSIC TENSILES OF THE THREE COMPOSITES WERE CLOSE AND APPROXIMATED A RULE OF MIXTURES ~~SO~~ AVERAGE OF THE TWO CONTROL BRAIDS. THE CARRIER BLEND WAS APPROX 10% HIGHER. INTRINSIC -KNOT STRENGTHS WERE VERY SIMILAR AMONG THE COMPOSITES AND WERE 75-80% OF THE PET CONTROL KNOT STRENGTH. THE COMM. HAD THE HIGHEST KNOT CONVERSION (79%). THE BENDING RIGIDITY OF THE COMMINGLED WAS HALF THE OTHER TWO COMPOSITES, PERHAPS REFLECTING THE MORE HOMOGENEOUS MIXTURE OF THE TWO COMPONENTS. ALL 3 COMPOSITES HAD KNOT SECURITYS OF 5 THROWS - SIGNIFICANTLY BETTER THAN 7 FOR 100% PTFE.

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002638

Investigator [signature] Date 2/2/89

Witness Crawford Britt Date 3-15-90

Page 36
Book No. 175

Project No. CBE Experiment No. Date 3/6/89
Subject VICRYL / PDS BRAID COMPOSITE
Purpose IN-VIVO DATA

BACKGROUND:
THE VICRYL / PDS COMPOSITE BRAIDS DESCRIBED ON PBS 10-11 WERE TESTED FOR IN-VITRO PROPERTIES.

THE FOLLOWING RESULTS WERE OBTAINED BY ERF (89-064):

SAMPLE	SIZE	0 DAY BASELINE (LBS)	21 DAY (LBS)	(%)
CBE-6	2-0	6.65	2.43	36.5
CBE-7	2-0	9.45	4.07	43.1
CBE-9	2-0	14.51	7.03	48.5
CBE-10	2-0	6.51	1.86	28.6

DISCUSSION
CBE-6 IS A CARRIER BLEND, CBE-7 IS YARN BLEND, CBE-10 IS PDS CONTROL. CBE-9 IS VICRYL CONTROL AND THE VICRYL CONTROL IS CLOSE TO PREVIOUS AVGS. THE 2 COMPOSITES FALL BETWEEN THE 2 CONTROLS AS EXPECTED, HOWEVER THE YARN BLEND RETAINED MORE STRENGTH AND WAS STRONGER TO START. THIS IS POSSIBLY DUE TO DIFFERENCES IN EXPOSURE HISTORY.

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C.A. No.04-12457 PBS
DMI002639

Investigator [signature] Date 3/6/89
Witness Crawford Britt Date 3-15-90

Project No. STU Experiment No. Date 4/11/89
Subject SURFACE-TREATMENT VICRYL
Purpose IDEA DOCUMENTATION

A SURFACE TREATMENT, SUCH AS PLASMA FLUORINATION WHICH LOWER THE SURFACE ENERGY OF AN ABSORBABLE SUTURE, MAY IMPROVE THE SUTURE'S BSR DUE TO INHIBITED WETTING OF THE SURFACE BY H_2O. IT IS SPECULATED THAT H_2O MUST FIRST BE ADSORBED ONTO THE POLYMER SURFACE BEFORE HYDROLYSIS (RESULTING IN CHAIN SCISSION AND STRENGTH DEGRADATION) CAN OCCUR SO THAT SLOWING THE ADSORPTION STEP BY MAKING IT MORE HYDROPHOBIC SHOULD SLOW THE TENSILE LOSS. ADDITIONAL PRODUCT IMPROVEMENTS MAY INCLUDE INCREASED PLIABILITY DUE TO INCREASED FIBER LUBRICITY AS WELL AS IMPROVED KNOT TIE-DOWN.

THE PROCESS WOULD PREFERABLY BE CONTINUOUS. FLUORINE ATOMS WOULD BE GRAFTED ONTO THE POLYMER BACKBONE, THE DEGREE DETERMINED BY THE RESIDENCE TIME AND CONCENTRATION OF THE PLASMA.

Investigator [signature] Date
Witness Crawford Britt Date 3-15-90

Page ......
Book No. ......
175

Project No. EI Experiment No. ...... Date 5/23/89
Subject KAWABATA BENDING RIGIDITY CHARACT
Purpose EVALUATE ETHIBOND STANDARD & EXTRA, TICRON

BACKGROUND:
THE BENDING RIGIDITY OF SIZE 2-0 ETHIBOND, ETH EXTRA, AND TI-CRON (D+G) WERE DETERMINED USING THE KAWABATA PURE BENDING TESTER AT P.C.T. t.s. SIX SAMPLES OF EACH WITH 36 STRANDS PER SAMPLE WERE TESTED (216 TOTAL) AS DESCRIBED ON PG 18.

RESULTS:

DESCRIP	SUTURE EI (GM·CM²/STRAND)	STD DEV
ETHIBOND/PRODUCTION/NON-STERILE	3.64 E-2	0.24 E-2
ETHIBOND/PRODUCTION/ Co 60	3.64 E-2	0.32 E-2
ETHIBOND EXTRA /NON-STERILE	2.16 E-2	0.22 E-2
TI-CRON /SILICONE/STERILE*	5.28 E-2	0.42 E-2

* HAND STRETCHED TO MINIMIZE MEMORY

ANALYSIS
THE DATA SUGGESTS: 1) SIGNIFICANTLY LOWER EI OR "IMPROVED PLIABILITY" FOR ETHIBOND EXTRA, 2) NO SIGNIFICANT EFFECTS OF Co 60 STERIL. ON PRODUCTION ETHIBOND EI, AND 3) LOWER EI OR HIGHER PLIABILITY OF CURRENT ETHIBOND VS TICRON. HOWEVER, IT SHOULD BE NOTED THAT THE BRAID M-K CURVES ARE NON-LINEAR SO THAT THE EI IS DEPENDENT ON WHERE THE SLOPE IS TAKEN. THE ABOVE DATA IS THE TIGHTER REGION OF CURVATURE (K=1.5 TO 2.5 cm⁻¹). IT SHOULD BE NOTED AT LOWER VALUES OF K THAT TICRON IS MORE PLIABLE THAN ETHIBOND STANDARD, BUT THAT ETHIBOND EXTRA EXHIBITS THE LOWEST EI OVER THE ENTIRE RANGE OF CURVATURE.

Investigator [signature] Date 5/23/89
Witness Pamela Britt Date 3-15-90

HERMES DECLARATION
EXHIBIT 7 – PART 2 OF 2

Page
Book No.
2175

Project No. VIP Experiment No. Date 6/12/89
Subject VICRYL IMPROVEMENT PROGRAM
Purpose SUMMARY OF PHASE I WORK

OBJECTIVE: TO IMPROVE CURRENT VICRYL BRAID IN TERMS OF HAND, STRENGTH OR BIOLOGICALS. THREE INDEPENDENT MODULES WERE EVALUATED: 1) FIBER CHEMISTRY-PROCESSING FOR IMPROVED TENACITY/BSR 2) YARN BUNDLE COHESIVENESS AND 3) BRAID RECONSTRUCTION

FIBER CHEM - PROCESSING

OBJ. EVALUATE THE PERFORMANCE (PHYSICAL PROPS, SUBJECTIVE HAND, BIOLOGICALS) OF BRAIDS PRODUCED WITH EXPERIMENTAL YARN FROM FIBER EXTRUSION DEPT (DR. MENEZES), WHICH VARIED IN CHEMISTRY AND PROCESSING CONDITIONS FROM CURRENT VICRYL.

EXPERIMENT
SUMMARY: THREE EXPERIMENTAL YARNS WERE EVALUATED: (1) ~~B~~ 97 PGA / 3 PLA, (2) 90/10 HIGH TENACITY PROCESS AND (3) 90/10 HIGH IV STANDARD PROCESS. THE PRIMARY OBJECTIVE OF (1) + (2) WERE IMPROVED BRAID STRENGTH (10-20) ~~WAS~~ + IMPROVED BIOLOGICALS, AND ONLY IMPROVED BIOLOGICALS FOR (3).

ALL 3 YARN MATERIALS WERE PROCESSED PER VICRYL 2-0 SPECIFICATIONS THROUGH BRAIDING, SCOURING, HOT-STRETCHING AND ANNEALING. ANNEALED BRAID WAS COATED WITH BOTH STANDARD CALCIUM STEARATE AND GLYCOLIDE CAPROLACTONE COMPOSITIONS. COATED BRAIDS WERE EO STERILIZED. BRAIDS WERE CHARACTERIZED FOR PHYSICAL PROPS AT ALL IN-PROCESS STAGES AND FOR SUBJECTIVE HAND AFTER ANNEALING + STERILIZATION STEPS.

RESULTS:
BRAID PHYSICAL PROPERTY DATA FOR ALL 3 MATERIALS AND CONTROLS THROUGH ANNEALING, COATING AND STERIL ARE GIVEN IN FOLLOWING TABLE

Investigator [signature] Date 6/12/89
Witness Crawford Britt Date 3-15-90

Page 04
Book No. 2175

Project No. VIP Experiment No. Date 6/12/89
Subject SUMMARY OF PHASE I
Purpose CONTINUED

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002643

RESULTS OF FIBER CHEM - PROCESS MODULE

VICRYL IMPROVEMENT PROGRAM
BRAID PHYSICAL PROPERTIES
FIBER CHEMISTRY/PROCESSING MODULE

SIZE	DESCRIPTION	PROCESS STAGE	LAB ID	DIAM (MILS)	TENSL (LBS)	INTRIN TENSL (KSI)	KNOT TENSL (LBS)	INTRIN KNOT TENS (KSI)	KNOT CONV (%)	ELONG (%)	SUBJ HAND 1:POOR 5:EXCL
2-0	97/3 PGA/PLA YARN	AN	A97-AN	12.88	17.92	137.5	10.05	77.2	56	16.48	3.5
2-0	97/3 PGA/PLA YARN	GC-ST	A97-G-S	13.78	18.45	123.7	10.19	68.4	53	19.57	0.0
2-0	90/10 HIGH IV,STD PROC.	AN	AHIV-AN	13.90	15.39	101.4	9.01	59.5	59	14.57	2.8
2-0	90/10 HIGH TENAC PROC	AN	AHT-AN	13.57	17.28	119.5	9.57	66.2	55	18.38	2.3
2-0	90/10 HIGH TENAC PROC	GC-ST	AHT-G-S	13.70	15.45	104.8	9.38	63.6	61	19.24	0.0
2-0	CONTROL (16x3, 56d)	AN	J07	13.52	15.09	105.1	8.88	61.9	59	14.76	3.0
2-0	CONTROL (16x3, 56d)	CaS	J09	13.28	15.37	110.9	9.86	71.1	64	19.20	3.0
2-0	CONTROL (16x3, 56d)	GIC	J10	12.94	15.42	117.3	9.40	71.4	61	16.06	4.4
2-0	CORNELIA PROC AVE	AN	Z27	12.96	15.32	116.2	8.98	68.1	59	17.16	0.0
2-0	CORNELIA PROC AVE	CaS	Z28	12.99	14.62	110.3	7.98	60.2	55	17.40	0.0

THE 97/3 DEMONSTRATED SIGNIFICANTLY IMPROVED TENSILE (18% INCR) AND KNOT STR (13% INCR) OVER PROCESS AVES. THE 90/10 HIGH TENACITY PROCESS DEMONSTRATED MARGINALLY IMPROVED TENSILE (3%) AND MARGINALLY INFERIOR KNOT VS PROCESS AVES. THE 90/10 HIGH IV DEMONSTRATED SIGNIFICANTLY INFERIOR PHYSICALS.

THE SUBJECTIVE HAND EVALUATION OF POST-ANNEALED BRAIDS IS SHOWN IN ~~FIGURE~~ THE LAST COLUMN OF THE ABOVE TABLE. CONTROLS WERE DEFINED A 3 RATING AND EXPERIMENTAL BRAIDS RANKED 1 (POOR) TO 5 (GOOD)

Investigator Date 6/12/89
Witness [illegible] Date 3-15-90

Page
Book No.
2175

Project No. VIP
Experiment No.
Date 6/12/89
Subject SUMMARY OF PHASE I
Purpose CONTINUED

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ACCORDINGLY. A SLIGHT PREFERENCE WAS SHOWN FOR THE 97/3 OVER THE 2-0 CONTROL OVER THE HIGH TENACITY 90/10. THE HAND OF ALL THREE DETERIATED SIGNIFICANTLY AFTER STERILIZATION.

CONCLUSIONS:

THE 97/3 DEMONSTRATED SIGNIFICANTLY IMPROVED PHYSICAL PROPS AND POTENTIALLY MINOR IMPROVEMENTS IN HAND AND SHOULD BE PURSUED FURTHER. THE 90/10 HT SHOULD WARRANT LOWER PRIORITY.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002644

YARN BUNDLE COHESIVENESS

OBJECTIVE:
TO EVALUATE THE EFFECT OF YARN TWIST ON: 1) BRAID INTRINSIC SMOOTHNESS + PLIABILITY, 2) GENERAL BRAID QUALITY AND 3) BRAID PHYSICAL AND BIOLOGICAL PROPERTIES.

EXPERIMENTAL SUMMARY:
TWO YARN TWIST LEVELS AND ONE NEW YARN LUBRICANT WERE EVALUATED ON SIZE 2-0 VICRYL (CONSTRUCTION: 16x3, 56 den). THE TWIST LEVELS WERE 3.0 AND 6.0 TPI (OR 3.0 TPI AND 6.1 TPI). THE PROPOSED FUNCTION OF THE TWIST IS TO INCREASE YARN BUNDLE COHESIVENESS (ROUNDER, TIGHTER MORE UNIFORM YARN BUNDLE) WHICH COULD TRANSLATE INTO A SMOOTHER, MORE UNIFORM BRAID. THE NEW YARN LUBRICANT, STANTEX 5260 (HENKEL CORP, CHARLOTTE NC), WAS APPLIED POST-EXTRUSION TO THE 56 den YARN WHICH WAS TWISTED TO 3.0 TPI ON A RATTI TWO-FOR-ONE TWISTER. SINCE THE STANTEX LUBRICANT WAS BELIEVED TO BE MUCH

Investigator [signature]
Date 6/12/89
Witness Crawford Britt
Date 3-15-90

Page ....
Book No. ....
2175

Project No. VIP Experiment No. .... Date 6/12/89

Subject SUMMARY OF PHASE I

Purpose CONTINUED

CONFIDENTIAL -
NON-PATENT
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LESS VISCOUS THAN THE CURRENT CMS/MINERAL OIL, IT WAS ANTICIPATED THAT THE TWISTED YARN WOULD BE LESS RIBBON-LIKE (WHICH CONTRIBUTES TO ROUGHNESS).

OTHER THAN TWIST AND LUBRICANT CONSIDERATIONS, THE EXPERIM. + CONTROL BRAIDS WERE PROCESSED PER THE 2-0 VICRYL SPEC. COATED BRAIDS WERE PROVIDED W/ CA STEARATE AND GLYC. CAPRAC. BRAIDS WERE CHARACTERIZED AT ALL IN-PROCESS STAGES + FOR SUBJECTIVE PROPS AFTER COATING.

RESULTS:
PHYSICAL PROPERTY DATA FOR THE YBC BRAIDS ARE GIVEN IN THE FOLLOWING TABLE.

VICRYL IMPROVEMENT MODULE
BRAID PHYSICAL PROPERTIES
YARN BUNDLE COHESIVENESS MODULE

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SIZE	DESCRIPTION	PROCESS STAGE	LAB ID	DIAM (MILS)	TENSL (LBS)	INTRIN TENSL (KSI)	KNOT TENSL (LBS)	INTRIN KNOT TENS (KSI)	KNOT CONV (%)	ELONG (%)	SUBJ HAND 1:POOR 5:EXCL
2-0	3 TM TWIST	AN	B26	13.64	15.60	106.8	9.23	63.2	59	16.51	3.6
2-0	3 TM TWIST	CaS	B28	13.60	15.40	105.7	8.50	58.5	55	18.54	2.5
2-0	3 TM TWIST	GlC	B29	12.94	14.89	111.4	9.31	70.8	63	15.41	3.6
2-0	6 TM TWIST	AN	B43	13.86	14.78	98.0	9.37	62.1	63	15.75	3.0
2-0	6 TM TWIST	CaS	B45	13.72	15.38	104.0	8.16	55.2	53	18.14	3.3
2-0	6 TM TWIST	GlC	B46	13.04	14.32	104.6	8.37	62.9	58	16.47	4.3
2-0	STANTEX LUB/ 3 TM	AN	B09	13.36	13.02	92.8	8.53	61.0	66	16.48	1.8
2-0	CONTROL (16x3, 56d)	AN	J07	13.52	15.09	105.1	8.88	61.9	59	14.76	3.0
2-0	CONTROL (16x3, 56d)	CaS	J09	13.28	15.37	110.9	9.86	71.1	64	19.20	3.0
2-0	CONTROL (16x3, 56d)	GlC	J10	12.94	15.42	117.3	9.40	71.4	61	16.06	4.4
2-0	CORNELIA PROC AVE	AN	ZZ7	12.96	15.32	116.2	8.98	68.1	59	17.16	0.0
2-0	CORNELIA PROC AVE	CaS	ZZ8	12.99	14.62	110.3	7.98	60.2	55	17.40	0.0

Investigator [signature] Date 6/12/89

Witness [signature] Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002645

Page .... Book No. ....
2175

Project No. VIP Experiment No. .... Date 6/12/89
Subject Summary of Phase I
Purpose Continued

Tensile strengths were 7-10% lower for the 3 + 6 Tm materials vs. controls, although knots were statistically equivalent. Only a marginal + inconsistent improvement in hand was observed in annealed and coated materials for the 3+6 Tm samples, with a signif. poorer hand observed for the 3 Tm Stantex sample.

The effect of yarn twist on variability of yarn tenacity is presented in table form:

VIP BUNDLE COHESIVENESS: YARN PROPERTIES (DYED 56d)

Lot #	Twist Tm	Lubric	Tenacity gpd	Tenacity %CV	Elongation %	Elongation %CV
XC3373	0	GMS/Min	5.86	5.22	19.99	5.02
XC3373	3	GMS/Min	5.76	7.29	22.26	6.02
XC3373	6	GMS/Min	6.03	8.43	21.91	3.53
USA-022	3	Stantex	5.78	3.72	25.38	5.83
88 Prod Avg.	0	GMS/Min	6.45	2.49	24.69	3.11

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Although lot variability is impossible to account for in such a small sampling (30 pulls on Statimat), it appears that the introduction of twist increases yarn variability. It should be noted that yn twist increases yarn failure elongation by 2-3% for the 3 + 6 Tm samples. No conclusions could be drawn on broken filament management by twist.
12 day invitro results were as follows:

	in vitro breaking str (lbs)	% retention
2-0 control	6.51	41.7
3 Tm twist	8.58	55.0
6 Tm twist	8.28	56.0

Investigator [signature] Date 6/12/89
Witness Crawford Britt Date 3-15-90

Page
Book No.
175

Project No. VIP Experiment No. Date 6/12/89
Subject SUMMARY OF PHASE I
Purpose CONTINUED

THE NATURE OF THIS IMPROVED BIOLOGICAL PERFORMANCE MAY BE THE RELOADING OF BROKEN FILAMENTS DUE TO THE TWISTED STRUCTURE, OR MAY SIMPLY BE AN ARTIFACT OF YARN/PROCESS VARIABILITY.

RECOMM:
PURSUE ON LOW PRIORITY FOR HAND IMPROVEMENT, BUT UNDERSTAND EFFECTS ON BSR + BROKEN FILAMENTS.

BRAID RECONSTRUCTION MODULE (MEDIUM SIZES)

OBJECTIVE:
TO DETERMINE WHETHER HAND IMPROVEMENTS COULD BE REALIZED BY CHANGES IN BRAID CONSTRUCTION IN MODEL SIZES 2-0 AND 1-0 VICRYL. THE PRIMARY FOCUS WAS ON UTILIZATION OF FINER DENIER SHEATH YARNS IN 24 + 16 CARRIER BRAID-ON-BRAID CONSTRUCTIONS TO FAVORABLY IMPACT SMOOTHNESS ON BRAID PROFILE.

EQUIPMENT/EXPERIMENT SUMMARY:
RATERA 24, 28, AND 32 CARRIER BRAIDERS + 16 CAR NE. BUTT WERE UTILIZED TO PRODUCE VICRYL BRAIDS IN THE 2-0 TO 1 SIZE RANGE. (NOTE: THE 28 AND 32 CARRIER CONSTRUCTS WERE FOUND TO BE FLAT AND HENCE ABANDONED). 24 CARRIER CONSTRUCTIONS WERE PRODUCED UTILIZING 14, 28, AND 40 den SHEATH YARNS; CORE CONSTRUCTIONS INCLUDED NON-TWISTED AND TWISTED YARN CONSTRUCTIONS, AND BRAIDED CORES. 16 CARR. BRAIDS WERE SIZES 2-0, 3-0, 4-0. + PRODUCED WITH 40 + 52 den SHEATH YARNS + 3-0 BRAIDED CORES.

Investigator [signature] Date 6/12/89
Witness [signature] Date 3-15-90

Page ...... Book No. 2175

Project No. VIP Experiment No. ...... Date 6/12/89
Subject SUMMARY OF PHASE I.
Purpose CONTINUED

ALL UTILIZED YARNS WERE STANDARD VICRYL 90/10 PROCESSED. OTHER THAN BRAIDING CONSIDERATIONS, THE MATERIALS WERE PROCESSED PER VICRYL SPECS. SAMPLES WERE COATED + CHARACTERIZED AS OTHER ~~RESULTS~~ VIP SAMPLES AND SURFACE PROFILOMETRY / MICROSCOPIC ANALYSIS.

RESULTS:
ALL ATTEMPTS TO UTILIZE 24 CARRIER CONSTRUCTIONS WITH TWISTED OR NON-TWISTED YARN ASSEMBLIES ~~AS~~ ~~BRAID~~ CORES RESULTED IN FLAT BRAIDS, ALTHOUGH OUTSTANDING SMOOTHNESS AND PLIABILITY WERE OBSERVED. (THE PHYSICAL PROPERTIES OF LAB TD E25b WITH A TWISTED CORE ARE INCLUDED IN THE RESULTS TABLE FOR COMPARISON PURPOSES) THE FLATTENING ISSUE WAS OVERCOME WHILE PRESERVING THE SMOOTHNESS GAINS, BY THE INCORPORATION OF A BRAIDED CORE OR "BRAID-ON-BRAID" CONSTRUCTION. THE BRAIDED CORE WITHIN THE SHEATH TUBE OR LUMEN OFFERS A HIGHER RESISTANCE TO TRANSVERSE COMPRESSION RELATIVE TO THE TWISTED YARN ASSEMBLY SO THAT FLATTENING EVEN IN THE 24 CARRIER CONSTRUCT. WAS MINIMIZED.

PHYSICAL PROPS OF THE MEDIUM SIZE RECONSTRUCTIONS ARE GIVEN IN THE FOLLOWING TABLE. D25f COMPARED FAVORABLY WITH THE CONTROL 2-0 IN SUBJECTIVE HAND AND POSSESSED STATIST. EQUIV. PHYSICALS. THE R_z PEAK-TO-VALLEY DISTANCE MEASURED BY SURFACE PROFILOMETRY DEMONSTRATED A 30-35% REDUCTION IN BRAID PROFILE FOR THE 24 CARRIER CONSTRUCTIONS VS CONTROLS, AND VALUES COMPARABLE TO TICRON 2-0.

PHYSICAL PROPS FOR 1-0 RECONSTRUCT. ARE ALSO GIVEN IN FOLLOWING TABLE. D25h EXHIBITED 10-15% HIGHER INTRINSIC TENSILE AND MARGINALLY HIGHER KNOTS

Investigator [signature] Date 6/22/89
Witness Crawford Britt Date 3-15-90

40
Page
Book No.
2175

Project No. VIP Experiment No. Date 6/12/89
Subject Summary of Phase I
Purpose Continued.

VS. CONTROLS, AND PERFORMED SIGNIFICANTLY BETTER IN THE SUBJ. HAND EVALUATION. ABSOLUTE AND NORMALIZED R_z DEMONSTRATE 30% REDUCTION IN BRAID PROFILE.

VICRYL IMPROVEMENT PROGRAM
BRAID PHYSICAL PROPERTIES
MEDIUM SIZE BRAID RECONSTRUCTION MODULE

SIZE	DESCRIPTION	PROCESS STAGE	LAB ID	DIAM (MILS)	TENSL (LBS)	INTRIN TENSL (KSI)	KNOT TENSL (LBS)	INTRIN KNOT TENS (KSI)	KNOT CONV (%)	ELONG (%)	SUBJ HAND 1:POOR 5:EXCL	Rz/r (PEAK -VALL /RAD)
2-0	24 CARRx28d,3-0 BRD COR	AN	D25f	14.88	19.72	113.4	10.42	60.0	53	16.29	4.4	0.101
2-0	24 CARRx28d,3-0 BRD COR	GC-ST	D32f	14.62	18.07	107.7	10.52	63.4	58	19.93	0.0	0.106
2-0	24 CARRx28d,4-0 BRD COR	AN	D25i	14.12	15.98	102.1	8.72	55.7	55	15.68	4.5	0.105
2-0	16 CARRx40d,3-0 BRD COR	AN	H25b	14.60	18.60	111.1	11.27	67.4	61	17.44	0.0	0.082
2-0	CONTROL (16x3, 56d)	AN	J07	13.52	15.09	105.1	8.88	61.9	59	14.76	3.0	0.158
2-0	CONTROL (16x3, 56d)	CaS	J09	13.28	15.37	110.9	9.86	71.1	64	19.20	3.0	0.000
2-0	CONTROL (16x3, 56d)	GLC	J10	12.94	15.42	117.3	9.40	71.4	61	16.06	4.4	0.000
2-0	CONTROL (16x3, 56d)	GC-ST	J16	12.88	14.48	111.2	9.24	71.0	64	17.75	0.0	0.130
2-0	CORNELIA PROC AVE	AN	Z27	12.96	15.32	116.2	8.98	68.1	59	17.16	0.0	0.000
2-0	CORNELIA PROC AVE	CaS	Z28	12.99	14.62	110.3	7.98	60.2	55	17.40	0.0	0.000
1-0	24 CARRx40d,3-0 BRD COR	AN	D25h	16.32	24.01	114.8	13.10	62.6	55	17.64	4.5	0.081
1-0	24 CARRx40d,3-0 BRD COR	CG-ST	D32h	16.40	21.95	103.9	13.25	61.7	60	20.25	0.0	0.000
1-0	24 CARRx28d,2-0 BRD COR	AN	D25e	16.76	23.24	105.1	12.92	58.6	56	16.10	4.3	0.098
1-0	16 CARRx52d,3-0 BRD COR	AN	H25a	15.30	21.59	117.4	11.62	65.5	61	19.02	0.0	0.092
1-0	CONTROL (16x3, 80d)	AN	K05	16.27	21.60	103.9	11.09	53.3	51	20.38	3.0	0.130
1-0	CORNELIA PROC AVE	AN	Z23	16.15	20.79	101.5	12.54	61.2	60	17.40	0.0	0.000
1-0	CORNELIA PROC AVE	CaS	Z24	15.99	20.63	102.8	11.37	56.6	55	18.95	0.0	0.000
1	24 CARRx52d,10x80d TV C	AN	E25b	17.54	27.83	115.1	17.30,	71.8	62	17.95	0.0	0.000

Investigator Date 6/12/89
Witness Date 2-15-90

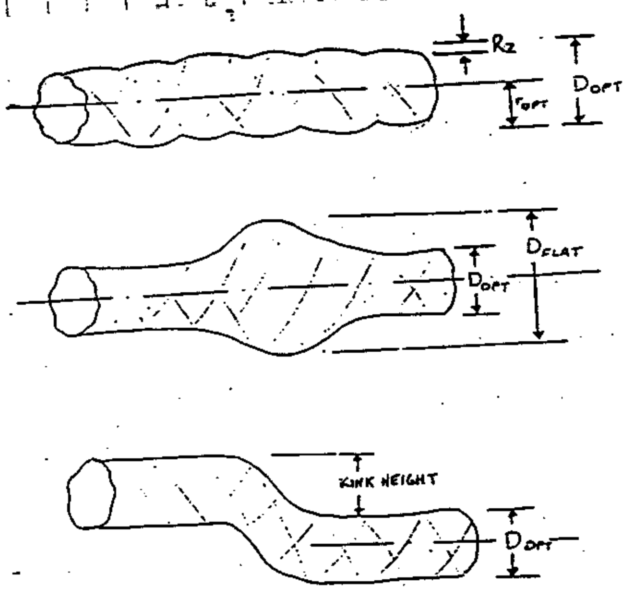
Page
Book No.
2175

Project No. VIP Experiment No. Date 6/12/89

Subject SUMMARY OF PHASE I

Purpose CONTINUED

24 CARRIER BRAIDS WERE JUDGED TO HAVE SUPERIOR HAND VS. CONTROLS AFTER STERILIZATION, HOWEVER THE MARGIN WAS REDUCED. DUE TO PERMANENT SETS OCCURRING DURING PACKAGING. TWO PRIMARY TYPES ~~OF~~ OF ROUGHNESS DEFECTS WERE OBSERVED: (1) LOCALIZED FLATTENING AT "FIGURE-8" CROSSOVER PTS AND BEND SECTIONS, AND (2) PERM. SET KINKS AT CROSSOVER POINTS. THE DEFECTS ARE SHOWN SCHEMATICALLY BELOW WITH WORST CASE DIMENSIONS:



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BRAID PROFILE ANALYSIS AFTER STERILIZATION
SIZE 2-0 CONTROL AND 24 CARRIER BRAID-ON-BRAID
WORST CASE MEASUREMENTS (MILS)

Lab ID	Diam (USP)	Diam (Optic)	Rz Anneal	Rz Coated Sterile	Diam. Flat Before Tug-Down	Diam. Flat After Tug-Down	Perm. Set Kink Before Tug-Down	Perm. Set Kink After Tug-Down
832f[1]	14.88	17.5	0.75	0.78	28.6	23.9	13	4.7
J16[2]	12.88	16.6	1.05	0.84	25.7	21.2	14	5.5

1 Construction (S=24x28d C=3-0 Braid)
2 Construction (S=16x56d C=3x56d)

Investigator Mark Steckel Date 6/12/89

Witness Crawford Britt Date 3-15-90

Page 40
Book No. 2175

Project No. VIP Experiment No. Date 6/12/89
Subject SUMMARY OF PHASE I
Purpose CONTINUED

THE MATERIALS WERE FIRST TUGGED DOWN ON A INSTRON (3.5 LBS FOR 2 SECS, 10 IN/MIN XHS) TO REMOVE INITIAL PACKAGE SET

RECOMMENDATIONS:

THE 24 CARRIER BRAID ALLOWS THE USAGE OF FINER DENIER YARNS WHICH TRANSLATE INTO A SMOOTHER BRAID. HOWEVER, WITHOUT CONCURRENT GAINS IN PACKAGING A LARGE FRACTION OF THE POTENTIAL IS LOST.

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Page
Book No.
2175

Project No. VIP Experiment No. Date 6/12/89
Subject SUMMARY OF PHASE I
Purpose CONTINUED

16 CARRIER BRAID-ON-BRAID CONSTRUCTIONS DEMONSTRATED SIMILAR SUBJECTIVE SMOOTHNESS AND PROFILOMETER SMOOTHNESS TO THE 24 CARRIER OF COMPARABLE SHEATH DENIER. A PENALTY IN STIFFNESS APPEARS APPARENT W/ THE 16 CARRIER DUE TO HIGHER CORE/SHEATH VOLUME FRACTION.

	Rz/r	COMMENTS
CONTROL - 16×3	0.158	J07
16×40d, 3-0 core	0.082	M25b
24×40d, 3-0 core	0.081	D25h

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Page ......
Book No. ......
175

Project No. SILK Experiment No. ...... Date 6/19/89

Subject SILK DEGUMMING + EFFECT ON UNSKEINING

Purpose DETERMINE CAUSE OF MANUF PROBLEMS

(2x2 13/15)

BACKGROUND:

TWO LOTS OF RAW AND DEGUMMED SILK PROVIDED BY MR JIM KRAMER OF CONNECLIA WERE ANALYZED DUE TO DIFFERENCES IN PROCESSABILITY IN UNSKEINING AFTER DEGUM SCOUR. LOT 88-24D CTN-4 RAN WITHOUT INCIDENT, WHEREAS LOT 88-24A CTN 17 RAN WITH A HIGH FREQ OF YARN BREAKS DURING UNSKEINING. THE RESULTS OF THE CHARACTERIZATION OF THE TWO LOTS ARE AS FOLLOWS (DEGUMMED):

PROPERTY	GOOD YARN 88-24D CTN-4	POOR YARN 88-24A CTN 17
TENSILE STRENGTH (GMS)	191.4 ± 35.9	188.7 ± 38.1
TWIST (TPI) (PLY)	16.9 ± 0.8	16.3 ± 1.1
DENIER	43	45
RESIDUAL GUM	VERY LOW LEVEL	MODERATE LEVEL

DISCUSSION:

TENSILE, TWIST + DENIER WERE STATISTIC. EQUIVALENT. HOWEVER, DIFFERENCES IN RESIDUAL GUM LEVEL (BY OPTICAL MICROSCOPY) WERE SIGNIFICANT. ALTHOUGH MAJORITY OF GUM WERE REMOVED IN BOTH CASES WHEN COMPARED TO RAW SILK, HIGHER LOCAL LEVELS WERE PRESENT IN THE POOR RUNNING YARN. IT IS PLAUSIBLE THAT THE TACKINESS OF THE RESIDUAL GUM LEVEL PREVENTS THE SKEIN FROM UNWINDING CLEANLY RESULTING IN YARN BREAKS.

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DMI002653

Investigator [signature] Date 6/19/89

Witness [signature] Date 3-15-90

Page 45

Book No. 2175

Project No. VIP Experiment No. Date 7/26/89

Subject BRAID STRESS - STRAIN PROPS

Purpose EVALUATE DIFFERENCES IN DEXON, VICRYL, PGA, 97/3

PROCEDURE:

THE BRAID STRESS-STRAIN BEHAVIOR WAS DETERMINED FOR 4 SIZE 2-0 BRAIDS: (1) VICRYL 90/10, (2) DEXON, (3) 100% PGA PROCESSED PER VICRYL SPEC, (4) 97/3 PGA/PLA PROCESSED PER VICRYL SPEC. ALL BRAIDS WERE STERILE AND PACKAGED, HOWEVER WHERE TUGGED DOWN BEFORE TESTING USING AN INSTRON (3.5 LBS - 2 SECS, 10"/MIN XHS). THE MATERIALS WERE TESTED USING THE FOLLOWING CONDITIONS: XHS: 300 mm/min, CS: 300 mm/min, GL 254 mm, FSL 10 KG, GRIPS 40PSI, FACES: RUBBER.

RESULTS

PROPERTY	VICRYL	DEXON	97/3	100% PLA
TENSILE STREN. (KG)	6.61	6.82	8.23	7.35
ULT ELONG (%)	19.00	~~29.13~~ 30.16	19.17	15.8
INIT MODULUS (GM/DEN)	67.45	55.80	74.70	77.42

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Page ....
Book No. ....
175

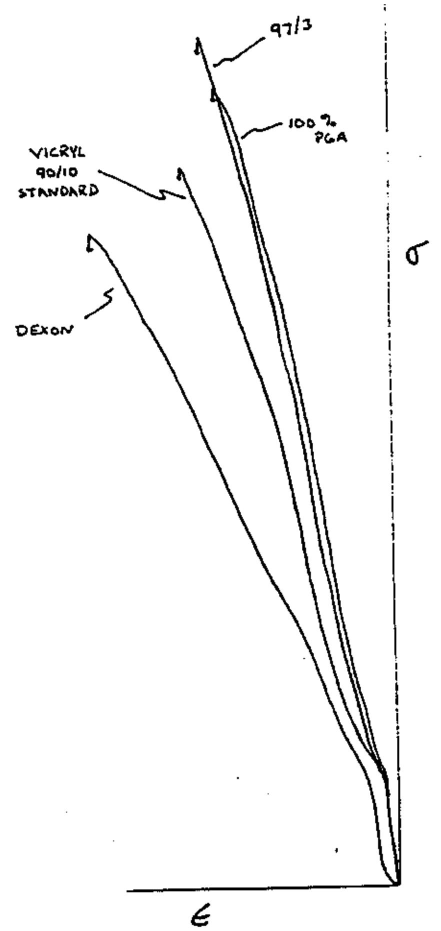
Project No. UIP Experiment No. .... Date 7/26/89

Subject Braid Stress-Strain Curves

Purpose Continued

The following are representative curves:

σ-ε Curves of Sterile 2-0 Braid



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Disicussion:

The Dexon braid possesses the lowest unit modulus (most likely reflecting an orientation level) and highest elongation. Also, the Dexon braid possesses an initial region of σ-ε typical of braid deformation. These attributes may contribute to the hand of Dexon vs Vicryl.

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Page
Book No. 2175

Project No. EI Experiment No. Date 8/11/89

Subject VICRYL 2-0 DYED - OFF-BRAIDER

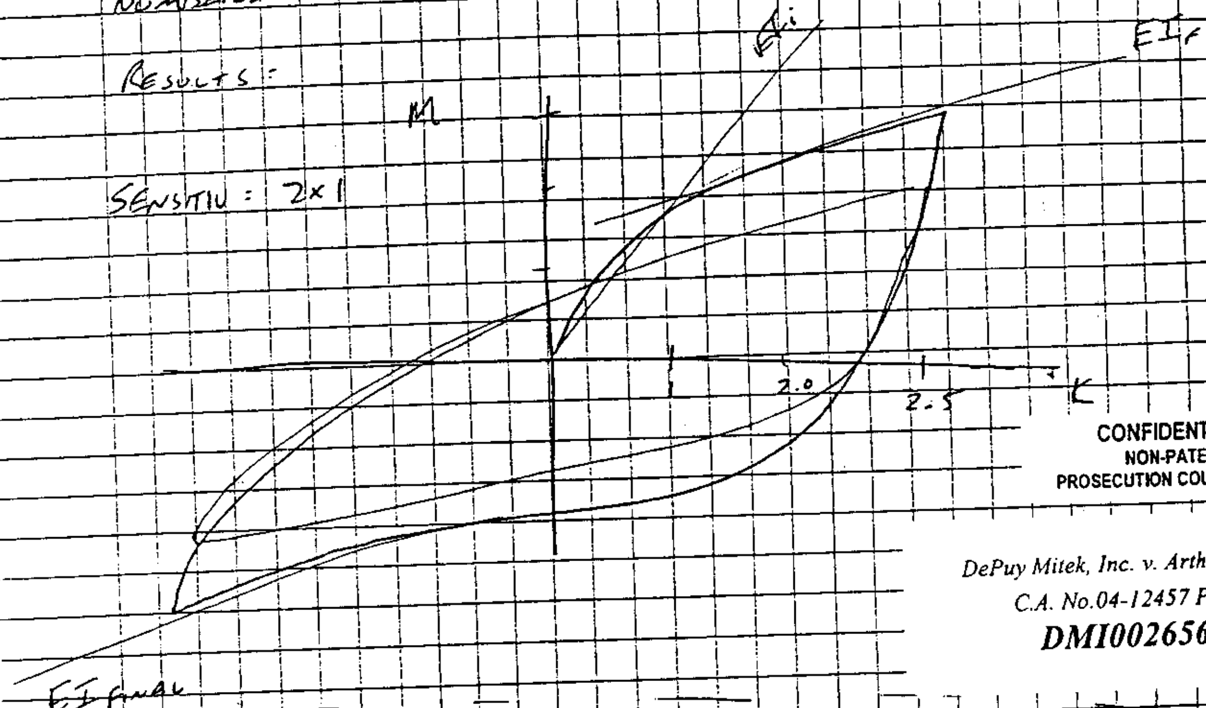
Purpose DETERMINE INITIAL + FINAL BENDING RIGIDITY

BACKGROUND / PROCEDURE:

VICRYL 3-0 VIOLET OFF-BRAIDER WAS TESTED ON THE KAWABATA PURE BENDING TESTER. STRANDS WERE MOUNTED ON PRE-CUT TABS WITH DOUBLE-STICK TAPE OR GLUE-STICK AND WOUND ON THE RACKWINDER. APPROX 50 STRANDS WERE WOUND + TRIMMED DOWN TO REQUIRED NUMBER.

RESULTS:

SENSITIV: 2x1



EI initial

SAMPLE (1)

N = 38

K	M
0	0
0.2	.09
0.4	.12
0.6	.14
0.8	.155
1.0	.168

SLOPE: 0.151

EI FINAL

	K	M
FORWARD:	1	.155
	3	.292
SLOPE:	0.0685	
BACKWARD:	-1	-.118
	-3	-.232
SLOPE:	0.057	

AVE = 0.063

$EI_i = \frac{0.151 \times 20}{38} = 7.94 \times 10^{-2}$ GM·CM²/STRAND

$EI_{final} = \frac{(0.063) \times 20}{38} = 3.3 \times 10^{-2}$ GM·CM²/STRAND

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40
Page
Book No.
175

Project No. EI Experiment No. Date 8/11/89
Subject NICRYL 2-0 BRAID
Purpose $EI_{initial}$ + EI_{final}

SAMPLE (2) EI_i EI_f

n = 39

K	M		K	M
0	0	FOWARD	1.0	.192
0.2	0.125		3.0	.378
0.4	0.162	SLOPE =	0.093	
0.6	0.185		K	M
0.8	0.202	BACKWD	-1	-.120
1.0	0.220		-3	-.255

SLOPE = 0.193

SLOPE = 0.068

$EI_i = \frac{(0.193)(20)}{39}$

$= 9.90 \times 10^{-2}$

AVE SLOPE = 0.080

$EI_f = \frac{(0.080)(20)}{39} = 4.12 \times 10^{-2}$

SAMPLE (3) EI_i

n = 39

	K	M
1	0	0
2	.2	.118
3	.4	.136
4	.6	.155
5	.8	.166
6	1.0	.180

E_f	K	M
1F	1	.156
2F	3	.275
SLOPE		0.0595
1B	-1	-.107
2B	-3	-.208
SLOPE =	0.0505	

SLOPE = 0.152

AVE SLOPE = 0.055

$EI_i = (0.152)(20)/39$

$= 7.79 \times 10^{-2}$

$EI_f = (0.055)(20)/39$

$= 2.82 \times 10^{-2}$

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SAMPLE (4) EI_i

n = 39

	K	M
1	0	0
2	.2	.142
3	.4	.175
4	.6	.20
5	.8	.215
6	1.0	.232

E_f	K	M
1F	1	.220
2F	3	.385
SLOPE		0.0825
1B	-1	-.11
2B	-3	-.242
SLOPE		0.066

SLOPE 0.20

AVE SLOPE 0.074

$EI_i = \frac{(0.20)\,20}{39} = 10.26 \times 10^{-2}$

$EI_f = \frac{(0.074)\,20}{39} = 3.81 \times 10^{-2}$

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49
Page
Book No.

2175

Project No. EI Experiment No. Date 8/11/89
Subject VICRYL 2-0 BRAID
Purpose EI, EI

SAMPLE (5) EI_i K M EI_f K M

n = 39

	K	M		K	M
1	0	0	1F	1	.210
2	.2	.125	2F	3	.390
3	.4	.155	SLOPE F	0.090	
4	.6	.175	1B	-1	-.120
5	.8	.190	2B	-3	-.255
6	1.0	.210	SLOPE B	0.0675	
	SLOPE = 0.181		SLOPE-AVE	0.0787	

$EI_i = \frac{(0.181)(20)}{39} = 9.28 \times 10^{-2}$ $EI_f = \frac{(0.0787)(20)}{39} = 4.04 \times 10^{-2}$

SAMPLE (6) EI_i K M EI_f K M

n = 39

	K	M		K	M
1	0	0	1F	1	.180
2	0.2	.132	2F	3	.316
3	.4	.150	SLOPE-F	0.068	
4	.6	.175	1B	-1	-.107
5	.8	.190	2B	-3	-.223
6	1.0	.202	SLOPE-B	0.058	
	SLOPE = 0.173		SLOPE-AVE	0.063	

$EI_i = \frac{(0.173)(20)}{39} = 8.88 \times 10^{-2}$ $EI_f = \frac{(0.063)(20)}{39} = 3.23 \times 10^{-2}$

SAMPLE (7) EI_i K M EI_f K M

n = 39

	K	M		K	M
1	0	0	1F	+1	.15
2	0.2	.122	2F	+3	.305
3	.4	.126	SLOPE-F	0.0775	
4	.6	.132	1B	-1	-.16
5	.8	.146	2B	-3	-.295
6	1.0	.161	SLOPE B	0.675	
	SLOPE = 0.126		SLOPE-AVE	~~0.0675~~ 0.0725	

$EI_i = \frac{(.126)(20)}{39} = 6.46 \times 10^{-2}$ $EI_f = \frac{(0.0725)(20)}{39} = 3.72 \times 10^{-2}$

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Page ....
Book No. ....
2175

Project No. EI Experiment No. .... Date 8/11/89
Subject VICRYL 2-0 BRAID - OFF-BRAIDER
Purpose CONTINUED

SAMPLE (8)
n=39

EI	K	M	EI_f	K	M
1	0	0	1F	1	.185
2	0.2	.117	2F	3	.350
3	0.4	.142	SLOPE-F	0.0825	
4	0.6	.170	1B	-1	-.090
5	0.8	.185	2B	-3	-.215
6	1.0	.195	SLOPE-B	0.0625	

SLOPE = 0.172 SLOPE-AVE 0.0725

$EI_i = \frac{(0.172)(20)}{39} = 8.82 \times 10^{-2}$ $EI_F = \frac{(0.0725)(20)}{39} = 3.72 \times 10^{-2}$

RESULTS SUMMARY

SAMPLE	EI_i	EI_F	
1	7.94	3.30	
2	9.90	4.12	
3	7.79	2.82	
4	10.26	3.81	
5	9.28	4.04	
6	8.88	3.23	
7	6.46	3.72	
8	8.82×10^{-2}	3.72×10^{-2}	
AVE	8.67×10^{-2}	3.60×10^{-2}	$gm \cdot cm^2$/STRAND
SD_{n-1}	1.23	0.44	
% CV	14.2%	12.2%	

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Page ....
Book No. ....
2175

Project No. 16212 Experiment No. .... Date 9/15/89
Subject SURFACE FLUORINATION OF VICRYL SUTURE
Purpose EVALUATION EFFECT ON HAND AND KNOT TIE-DOWN

BACKGROUND: SAMPLES OF SIZE 2-0 VIOLET VICRYL BRAID LOT # A3801 (CORNELIA) AFTER SCOURING WERE PROCESSED BY TEKMAT CORPORATION OF ASHLAND MASS. THREE PROCESS CONDITIONS OF THE FLUORINE SURFACE PLASMA TECHNIQUE WERE PERFORMED BY TEKMAT AND RETURNED. THE SAMPLES HAVE BEEN LABELED:

A3801 - OB - T1	(TREATMENT 1)
A3801 - OB - T2	" 2
A3801 - OB - T3	" 3
A3801 - OB - C	CONTROL - NO TREATMENT

PROCEDURE + RESULTS:
SAMPLES WERE EVALUATED FOR HAND + TIE-DOWN BY MGS. THE SAMPLES T1, T2, T3 WERE ALL WORSE THAN THE CONTROL FOR HAND PRIMARILY DUE TO A GROSS UNDULATION OR ROUGHNESS IN THE BRAID. IT APPEARS THAT THE BRAIDS WERE SUBJECTED TO A THERMAL TREATMENT W/O TENSION AND THAT THE FREE RELAXATION ALLOWED DIFFERENTIAL SHRINKAGE IN THE BRAID. SAMPLE 3 HAD THE MOST PRONOUNCED EFFECT, SAMPLES 1 AND 2 WERE COMPARABLE + SIGNIFICANTLY WORSE THAN THE CONTROL.

IN TERMS OF KNOT TIE-DOWN, SAMPLE 3 WAS SLIGHTLY BETTER THAN THE CONTROL. A STABLE SLIDING ACTION WAS OBTAINABLE for EAR AT LEAST ON EARLY THROWS (AS OPPOSED TO THE DRAMATIC STICK-SLIP ACTION OF T1, T2 AND THE CONTROL. EVEN THOUGH, T3 WAS STILL SIGNIFICANTLY ROUGHER AND RASPIER THAN ~~TO~~ A COATED VICRYL SUTURE IN TIE-DOWN AND WOULD MOST LIKELY NOT BE SUITABLE FOR GENERAL APPLICATION IN THE NON-COATED FORM.

Investigator [signature] Date 9/15/89
Witness Crawford Britt Date 3-15-90

Page 10
Book No. 175

Project No. MFE Experiment No. ______ Date 10/19/89

Subject MICROFIBER EVALUATION

Purpose EVALUATE THE BENDING + TENSILE PROPERTIES OF FINE DPF POLYESTER YARNS VS. CONVENTIONAL DACRON YARN

MATERIALS:

			dpf
ASAHI (JAPAN)	110/1100 PET	(den / # FILAMENTS)	0.1
ASAHI	50/96 PET		0.52
DACRON (DUPONT)	110/34/T52 PET		3.23
DACRON	55/27/T52 PET		2.0

PROCEDURE:

THE ABOVE 4 TYPES OF PET WERE INDIVIDUALLY BRAIDED IN 8x1 CONSTRUCTIONS USING NE BUTT BRAIDERS; CONDITIONS: 34 PG, SH SPRING = 0.009" DIAM x 5", TEXTROL CORE TENSION 12-18 GMS). THE BRAIDS WERE THEN HOT-STRETCHED USING THE ETHIBOND HOT-PLATE AT 400°F AND 15%, 4.90 FPM TAKE-UP AND 8 WRAPS ON ROLL 1 AND 8 WRAPS ON ROLL 2. THE SAMPLES WERE LABELED AS FOLLOWS:

BRAID ID	YARN
MFE-01	ASAHI 110 d / 0.1 dpf
MFE-02	DACRON 110d / 3.23 dpf
MFE-03	ASAHI 50 d / 0.52 dpf
MFE-04	DACRON 55d / 2.0 dpf

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RESULTS

THE FOLLOWING DIAM., TENSILE, AND KNOT STRENGTHS WERE DETERMINED:

SAMPLE	DIAM (MILS)	BREAK STR (LBS)	INTRIN TEN STR (PSI)	(LBS) KNOT STR	(PSI) KNOT INTRIN	(%) TENSILE EF
MFE-01	12.87	7.704	59,220	4.320	33,200	7.3
MFE-02	12.84	13.80	106,500	7.414	57,300	12.9
MFE-03	7.48	5.27	119,900	2.933	66,700	7.8
MFE-04	8.820	7.58	124,100	3.952	64,810	8.37

Investigator Mel Shalaby Date 10/19/89

Witness Rosalind Britt Date 3-15-90

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Page
Book No.
2175

Project No. MFE Experiment No. Date 10/19/89

Subject

Purpose CONTINUED FROM p52

THE SAME BRAIDS WERE TESTED WITH THE KAWABATA PURE BENDING TESTER FOR INITIAL AND FUNCTIONAL (2ND CYCLE) EI (gm·cm²/STRAND)

SAMPLE	DIAM	$EI_{STRAND, INITIAL}$	$EI_{STRAND, FUNC (2ND CYCLE)}$
MFE-01	12.87	46.1×10^{-2}	15.6×10^{-2}
MFE-02	12.84	14.8×10^{-2}	
MFE-03	7.48	28.8×10^{-2}	3.03×10^{-2}
MFE-04	8.82	16.4×10^{-2}	3.09×10^{-2}

TO NORMALIZE THE ABOVE RESULTS FOR DIAMETER, THE (I_z) MOMENT OF INERTIA CAN BE CALCULATED FROM THE RADIUS OR ($\pi d^4/32$) SO THAT E (COMPOSITE TENSILE & COMPRESSIVE MODULUS) CAN BE DETERMINED

dPF	SAMPLE	I_z (cm⁴)	$E_{STRAND, INITIAL}$ (gm/cm²)	$E_{STRAND, FUNCTIONAL}$ (gm/cm²)	DIAM (cm)
0.1	MFE-01	1.11×10^{-7}	4.19×10^{6}	1.40×10^{6}	3.26×10^{-2}
3.23	MFE-02	1.11×10^{-7}	1.33×10^{6}		3.26×10^{-2}
0.52	MFE-03	1.25×10^{-8}	2.30×10^{7}	2.42×10^{6}	1.89×10^{-2}
2.0	MFE-04	2.47×10^{-8}	6.64×10^{6}	1.25×10^{6}	2.24×10^{-2}

DISCUSSION:

NEXT PAGE

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Witness Crawford Britt Date 3-15-90

Page ......
Book No. ......
175

Project No. MFE Experiment No. ...... Date 10/19/89
Subject Microfiber Evaluation
Purpose Cont. from p53

INITIAL MODULUS (E) DERIVED FROM BENDING TESTS AS A FUNCTION OF DPF FOR PET

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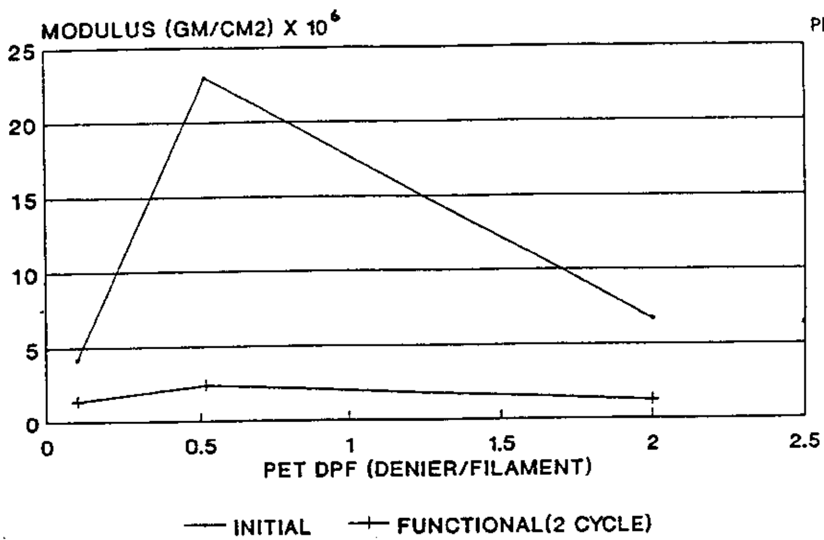

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E= EI/I WHERE $I = \pi r^4/32$

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Discussion:

Pliability or Bending Rigidity is ~~a function~~ dependent on several factors in braided sutures including: 1) fiber modulus, 2) fiber diameter & shape, 3) braid construction, 4) fiber surface props such as lubricant type, intrinsic surface tension, ~~and~~ 5) hot-stretch conditions which determine fiber/yarn bundle packing and degree of mechanical interlocking or fiber mobility. From simply the fiber diameter viewpoint, lower DPF should result in lower EI since $I = \pi r^4/32$. However lower DPF ~~as~~ also means higher fiber surface area which ~~can~~ can affect fiber/yarn packing, the degree of fiber mobility and the contribution of fiber-fiber interactions. Evidently in the products tested, the fiber interaction affects dominated over the fiber fineness. Two points should be noted: 1) the fiber modulus was not constant for all 3 samples; the 0.52 was probably higher than 0.1, and 2) the products were hot-stretched at conditions optimized for 2.0 DPF product, which may be too severe for 0.1 + 0.52 DPF fibers.

Investigator [signature] Date 10/19/89
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55 Page ......
Book No. 2175

Project No. IDEA Experiment No. ...... Date 11/16/89

Subject EXPANDED MONOFILAMENT WITH MULTIFILAMENT PROPS

Purpose DOCUMENT CONCEPTION OF INVENTION

IDEA: A SUTURE CAN BE PRODUCED WHICH APPEARS TO BE A MONOFILAMENT EVEN AT LOW MAGNIFICATION (10x) BUT WHICH BEHAVES LIKE A MULTIFILAMENT BRAID IN TERMS OF PLIABILITY / HANDLING PROPS BY "EXPANDING" THE CONTINUUM OF POLYMER INTO A PLURALITY OF MICROFIBRILS. THIS TECHNOLOGY IS APPLIED TO PTFE IN THE FORMATION OF THE GORE SUTURE. HOWEVER, THE PTFE EMBODIEMENT HAS DISADVANTAGES, MOST NOTABLY LOW STRENGTH AND KNOT SECURITY. THIS COULD BE IMPROVED UPON BY APPLYING THE TECHNOLOGY TO HIGHER STRENGTH POLYMERS, SUCH AS PE AND PP. A HIGH CRYSTALLINITY POLYMER (PREFERRABLY > 55%) IS NECESSARY FOR THIS APPROACH IN ORDER TO FORM THE MICROFIBRILLAR STRUCTURE. THIS HIGH CRYSTALLINITY CAN BE MADE POSSIBLE BY THE USE OF VERY PURE HIGH MW POLYMER, AND BY CONTROLLING THE SPINNING AND ORIENTATION CONDITIONS, AS WELL AS BY A POST - ORIENTATION ANNEALING OPERATION. THE MONOFILAMENTS ARE CONVERTED INTO THE EXPANDED STRUCTURE BY A "COLD-DRAWING" OPERATION, WHERE THE FILAMENTS ARE EXTENDED BETWEEN GODETS AT A HIGH RATE AT AMBIENT OR MINIMAL THERMAL EXPOSURE. ALTERNATIVELY, A SIMILAR STRUCTURE CAN BE OBTAINED BY SOLVENT SPINNING WHERE THE SOLVENT REMOVAL RESULTS IN A PORE STRUCTURE WHICH IS THEN ORIENTED.

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Investigator [signature] Date 11/16/89

Witness Crawford Britt Date 3-15-90

Page
Book No.
175

Project No. CBE Experiment No. Date 12/13/89
Subject PREFERRED CONSTRUCTION FOR PTFE/PET COMPOSITE BRAID
Purpose PROPRIETARY BRAID WITH IMPROVED HANDLING PROPERTIES

BACKGROUND: (PG 26). PTFE/PET CARRIER BLENDS HAVE BEEN FOUND TO OFFER EXCEPTIONAL HANDLING PROPERTIES FOR A BRAIDED SUTURE.

CONSTRUCTION:
A CARRIER BLEND COMPOSITE BRAID IS PRODUCED USING PTFE YARNS AND PET YARNS. THE SHEATH x CORE COUNT IS 16x 3. THE SHEATH CARRIER LAYOUT IS 2 PTFE, 2 PET, 2 PTFE ... WHICH INSURES A TORSIONALLY STABLE BRAID SINCE AN EQUAL # OF CARRIERS EXIST IN THE CW AND CCW DIRECTIONS. THE CORE YARNS ARE ALL PET FOR ADDED STRENGTH. THE PTFE YARNS ARE 75 den / 12 FILAMENT MANUFACTURED BY SHOWA (JAPAN), THE PET YARNS ARE 55 DEN/27 FILAMENT / TYPE 57 MANUFACTURED BY DuPONT. THE TOTAL VOLUME FRACTION OF EACH COMPONENT ARE: PTFE 56%, PET 44%.

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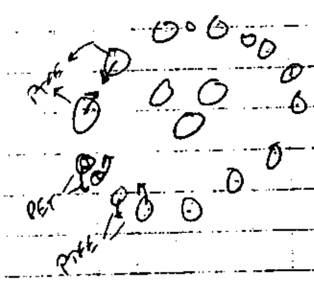
PROCESSING:
THE YARNS WERE WOUND ON BOBBINS PER STANDARD METHODS AND PLACED ON THE BRAIDER PER FIG. 1. A 0.5 OZ WAS USED FOR TENSION ON THE PET YARN, NO YARN TENSION SPRING WAS USED ON THE PTFE. A 32 PICK GEAR WAS USED RESULTING IN 42 PPI. CORE TENSION WAS ADJUSTED TO 30 GMS. AFTER BRAIDING, THE SUTURE WAS SCOURED AND HOT-STRETCHED OVER A HOT-PLATE AT 400°F AND 15% STRETCH RATIO. SUBSEQUENTLY, THE SUTURE WAS PASSED THROUGH A 11 MIL DIE AFTER PASSING THROUGH A FORCED AIR OVEN AT 300°F.



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002665

Investigator [signature] Date 12/13/89
Witness [signature] Date 3-15-90

Page ......
Book No. ......

2175

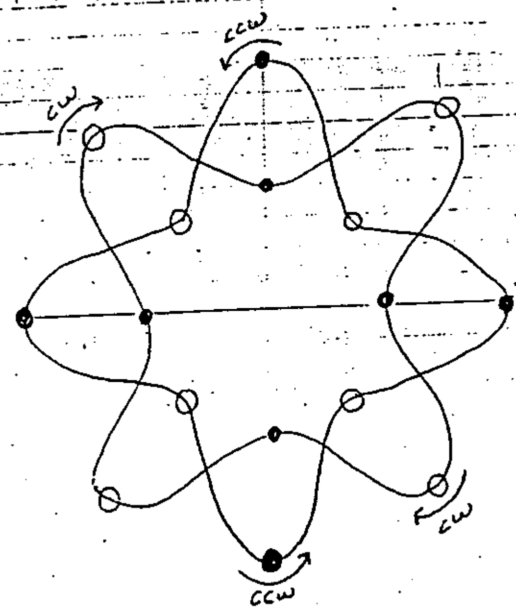
Project No. CBE Experiment No. ...... Date 12/13/89

Subject CONTIN. FROM 2175-56

Purpose

PROPERTIES:

THE DIE-DRAWN COMPOSITE BRAID HAD SUPERIOR HANDLING PROPERTIES RELATIVE TO SILK AND ETHIBOND, WHICH IS DEMONSTRATED QUANTITATIVELY IN FIG 2 OF THE KAWABATA BENDING RIGIDITY RESULTS. THE INTRINSIC TENSILE AND KNOT STRENGTHS WERE 87 KSI AND 48 KSI RESPECTIVELY. THE COMPOSITE ALSO RANKED BETTER THAN THE SILK AND ETHIBOND IN KNOT TIE-DOWN, EVEN WITHOUT A COATING.



MS 12/13/89

FIG. 1. SCHEMATIC OF CARRIER LAY OUT FOR BALANCED COMPOSITE BRAID.

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C.A. No.04-12457 PBS
DMI002666

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Page
Book No.
175

Project No. CBE Experiment No. Date 12/13/89
Subject Continued from 57
Purpose

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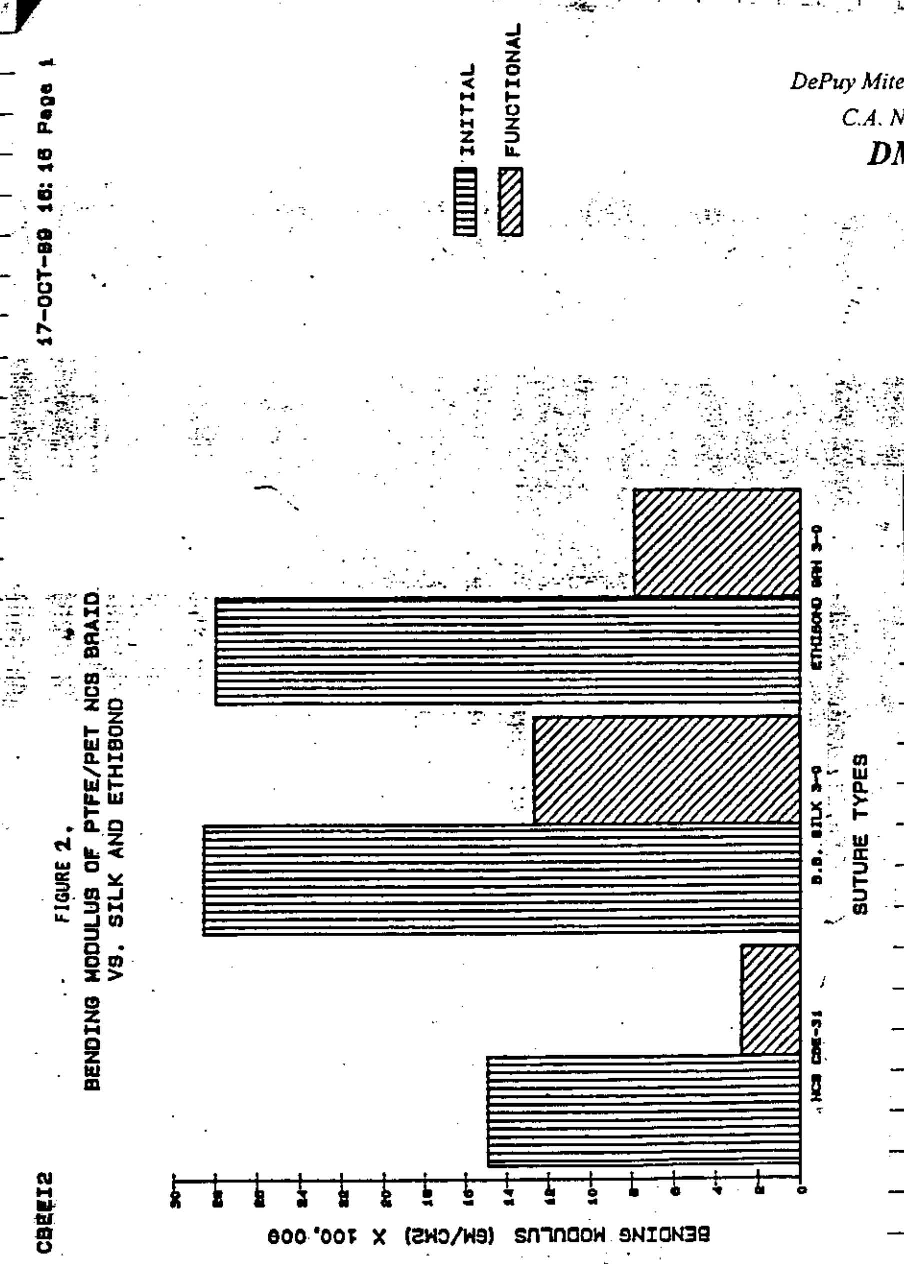
DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002667



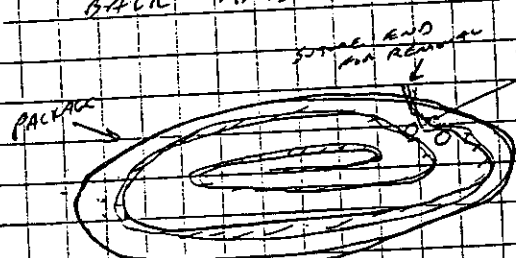
MS
12/13/89

Investigator [signature] Date 12/13/89
Witness [signature] Date 3-15-90

Page
Book No.
2175

Project No. IDEA Experiment No. Date 12/19/89
Subject PLIABILIZING PINS IN SUTURE PACKAGE
Purpose TO IMPROVE PLIABILITY OF SUTURE IN USE.

IDEA: THE BENEFITS OF "MECHANICAL PLIABILIZATION"
HAVE LONG BEEN RECOGNIZED TO IMPROVE THE
HAND OF BRAIDED SUTURES. THE APPROACH IS TO
BREAK UP THE WEAK ADHESIONS WHICH BIND
TOGETHER INDIVIDUAL MULTIFILAMENTS IN THE
BRAID BUNDLE. THESE ADHESIONS ACT TO REDUCE
FIBER MOBILITY AND EFFECTIVELY INCREASE THE
BENDING RIGIDITY OR STIFFNESS OF THE BRAID.
THE ADHESIONS ARE GENERALLY DISRUPTED BY FORCING
THE BRAID INTO ONE OR MORE SHARP CURVATURES
WHICH HAVE THE EFFECT OF SHEARING OR SLIDING
THE FIBERS RELATIVE TO EACH OTHER THROUGH
THE THICKNESS OF THE BRAID. HOWEVER, THIS
OPERATION IS CONVENTIONALLY PERFORMED AFTER
HOT-STR., ANNEALING, OR COATING. THE BRAID
EXPERIENCES ELEVATED TEMPS DURING STERIL. +
PACKAGING CYCLES, WHICH CAN REFORM THE
ADHESIONS. THE PROPOSED INVENTION IS TO INCLUDE
PLIABIZATION PINS OR ROLLS INTO THE DESIGN
OF THE PACKAGE SO THAT THE MANUAL
REMOVAL OF THE SUTURE IMPARTS A
PLIABILIZATION EFFECT ON THE SUTURE.
IT HAS BEEN SHOWN REPEATED THAT THE KAWABATA
PLIABILITY AS MEASURED BY THE SIGNIFICANTLY
PURE BENDING TESTER IS ALMOST ALWAYS
HIGHER IN THE 1ST CYCLE VS 2ND CYCLE, DUE TO
THE PLIABILIZING EFFECT OF BENDING THE ONCE
BACK AND FORTH. THIS EFFECT WOULD BE
BENEFICIAL TO BOTH
MULTIFILAMENT AND
MONOFILAMENT SUTURES.



THE PACKAGE COULD BE
INJECTION MOLDED SO THAT
THE PINS WOULD BE AN
INTEGRAL PART.

Investigator [signature] Date 12/19/89
Witness Crawford Britt Date 3-15-90

Page 00
Book No. 2175

Project No. TEKMAT Experiment No. Date 1/8/90

Subject IN VIVO RESULTS OF SURFACE FLUORINATED VICRYL BRAID

Purpose IMPROVE THE BSR OF VICRYL W/O ANNEALING

BACKGROUND: TO IMPROVE THE HYDROLYTIC RESISTANCE OF VICRYL AND EXTEND THE BSR, VICRYL BRAID IS ANNEALED. THIS ANNEALING OPERATION IMPROVES CRYSTALLINITY, BUT ALSO CAN ADD STIFFNESS TO THE BRAID. THE APPROACH TRIED HERE WAS TO TREAT THE SURFACE TO RENDER IT HYDROPHOBIC, SO THAT WATER WOULD ADSORB AND DIFFUSE AND DEGRADE THE VICRYL AT A SLOWER RATE. TEKMAT INC OF ASHLAND MASSACHUSETTS ATTEMPTED TO SURFACE FLUORINATE VICRYL BRAID AT THREE LEVELS. NO PROCESS DETAILS ON THE LEVELS WAS MADE AVAILABLE BY TEKMAT.

RESULTS:
THE FOLLOWING TABLE SUMMARIZES THE 0, 7, 21 DAY INVIVO RESULTS OF THE VICRYL FOR THE THREE LEVELS OF TREATMENT AND A CONTROL. THE BRAIDS WERE SCOURED BUT NOT HOT-STRETCHED OR ANNEALED. No STATISTICAL DIFFERENCES WERE OBSERVED BETWEEN THE TREATED SAMPLES AND THE CONTROL, SUGGESTING THAT THE TREATMENT WAS NOT EFFECTIVE.

AVERAGE BREAKING STRENGTH VALUES FOR VICRYL SUTURES
AFTER SUBCUTANEOUS IMPLANTATION IN RATS.
DATA EXPRESSED IN POUNDS

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		TIME IN DAYS		
SAMPLE NUMBER	SIZE	0	7	21
A3801-OB-T1	2-0	12.76	6.00	0.00*
PERCENT REMAINING		100	47	0
A3801-OB-T2	2-0	13.32	5.74	0.00*
PERCENT REMAINING		100	43	0
A3801-OB-T3	2-0	14.06	6.41	0.00*
PERCENT REMAINING		100	46	0
A3801-OB-C	2-0	14.41	6.20	0.00*
PERCENT REMAINING		100	43	0

MS 1/8/90

*THESE ARE AVERAGES DERIVED FROM BOTH INSTRON VALUES AND TECHNICAL JUDGEMENTS OF ZERO NECESSITATED BY UNMEASURABLE SAMPLES.

FUTURE WORK: THE TREATMENT WILL BE ATTEMPTED ON PDS MONOFILAMENTS.

Investigator [signature] Date 1/8/90
Witness Crawford Britt Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002669

Page .... Book No. 2175

Project No. BCAD Experiment No. .... Date 2/21/90

Subject HOT-STRETCHED MODEL BRAIDS

Purpose PROVIDE DATA FOR FORMULATION AND VALIDATION OF HOT-STRETCH MODEL

BACKGROUND: THE BRAID CAD SOFTWARE CAN CURRENTLY PREDICT KEY GEOMETRIC AND MECHANICAL PROPERTIES FOR OFF-BRAIDER SUTURE. IN ORDER TO FORMULATE THE MODULE TO PREDICT HOT-STRETCHED BRAID PROPERTIES, A MODEL BRAID WAS PROCESSED BY A VARIETY OF CONDITIONS AND CHARACTERIZED TO GIVE DIRECTION TO THE EFFECT OF HOT-STRETCH RATIO ON BRAID PROPERTIES.

EXPERIMENT:

AN 8x1, 70 den TYPE 52 DACRON POLYESTER BRAID WAS PROCESSED WITH A 34 PICK GEAR. THE BRAID WAS HOT-STRETCHED ON THE "ETHIBOND" HOT-PLATE AT 400°F AT THE FOLLOWING STRETCH RATIOS: 5, 10, 15, 20, 25%.

RESULTS:

THE RESULTS ARE SUMMARIZED IN THE FOLLOWING PLOTS:

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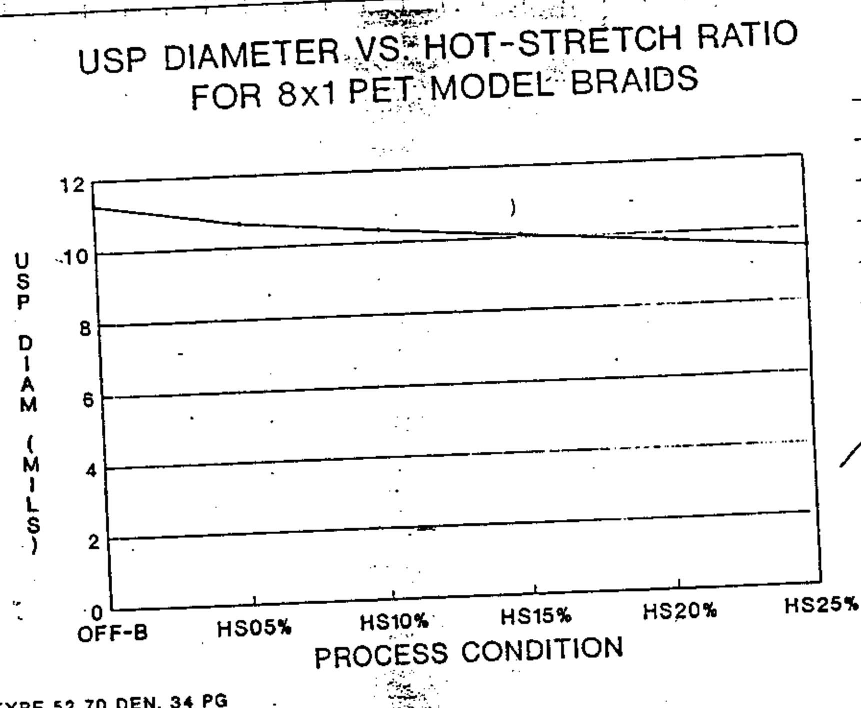


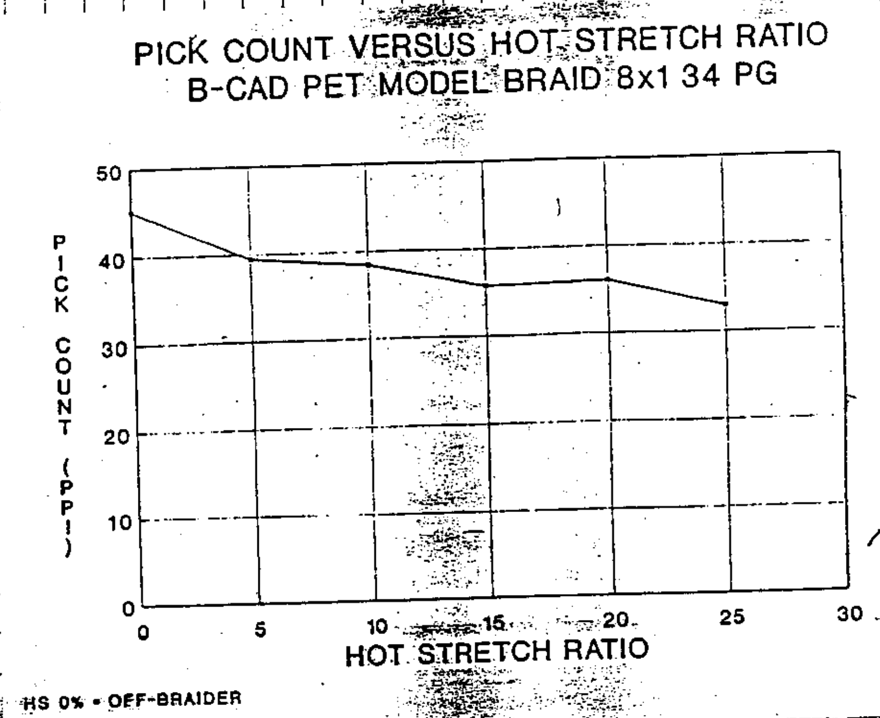
MS 2/21/90

Investigator [signature] Date 2/21/90

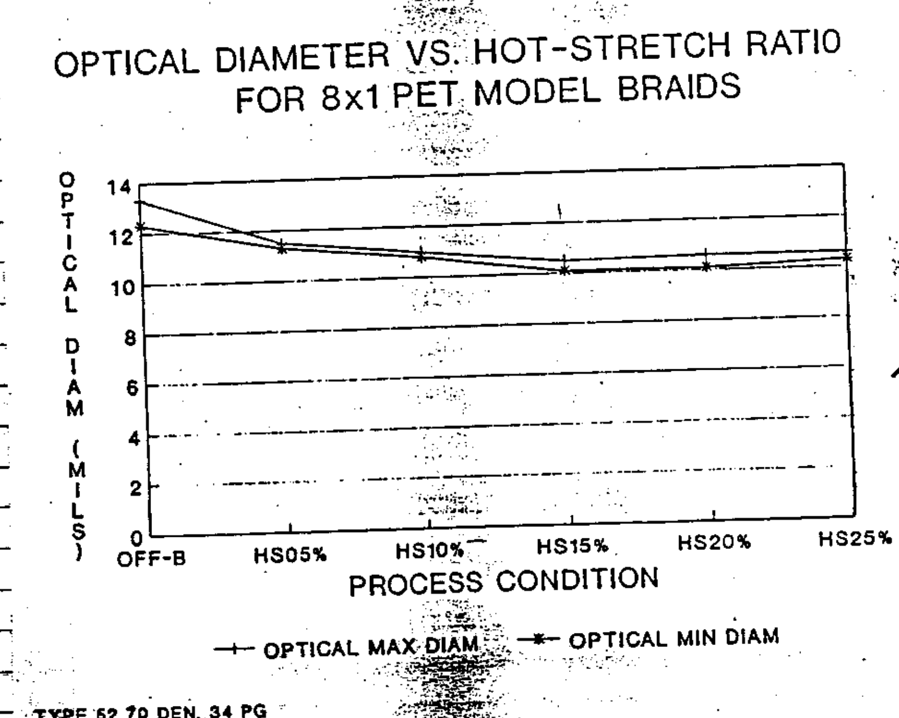
Witness Crawford Britt Date 3-15-90

62
Page
Book No. 2175

Project No. B-CAD Experiment No. Date 2/21/90
Subject HOT-STRETCH MODELS
Purpose CONTINUED FROM p-61



MS 2/21/90

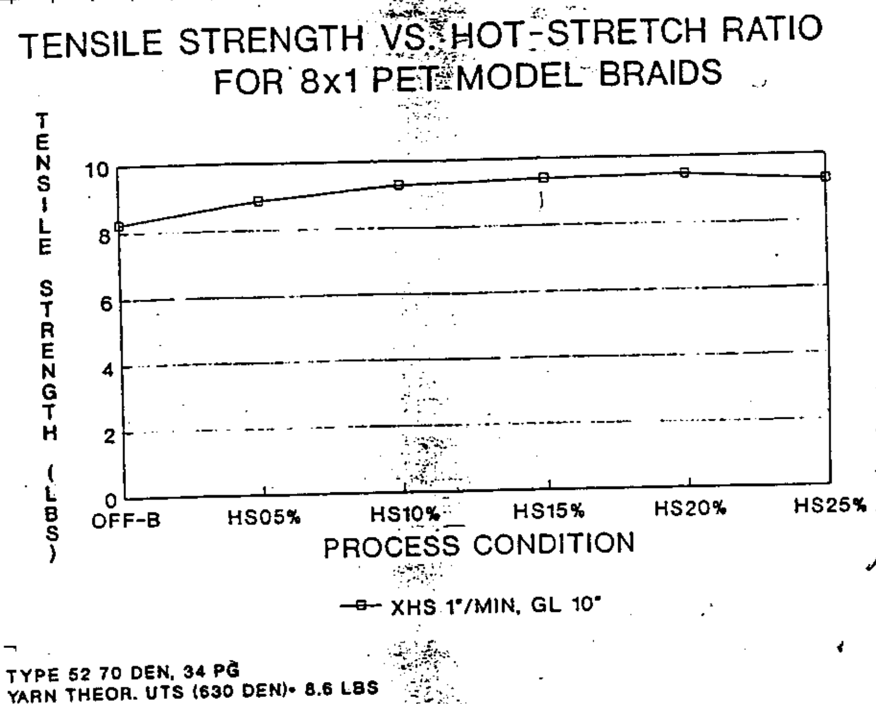


MS 2/21/90

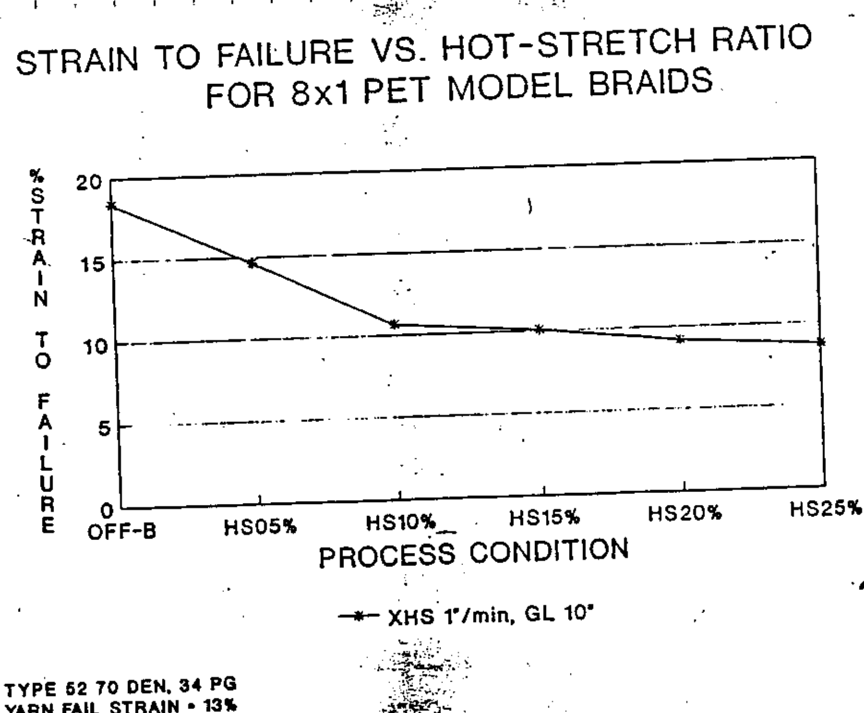
Investigator [signature] Date 2/21/90
Witness Date

63 Page
Book No.
2175

Project No. B-CAD Experiment No. Date 2/21/90
Subject HOT-STRETCH MODELS
Purpose CONTIN. FROM p-62



MS 2/21/90



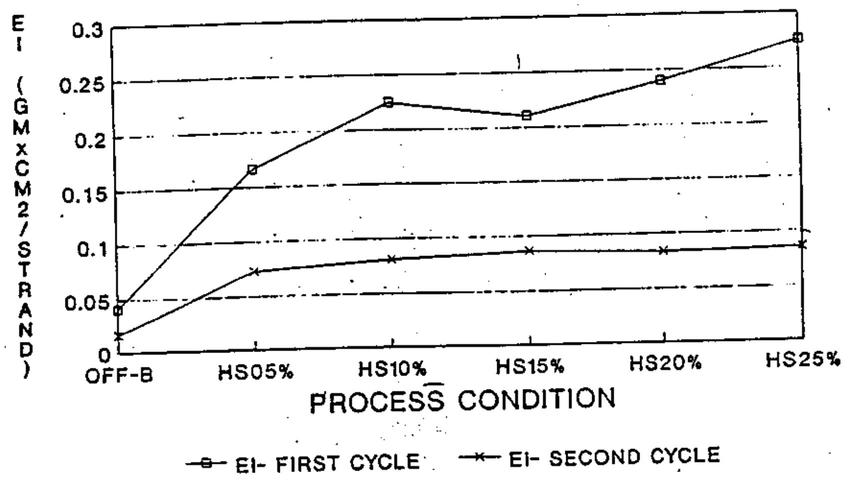
MS 2/21/90

Investigator Mark Steckel Date 2/21/90
Witness Crawford Britt Date 3-15-90

Page ....
Book No. 2175

Project No. BCAD Experiment No. .... Date 2/21/90
Subject HOT STRETCH MODELS
Purpose CONT FROM P. 63

BENDING RIGIDITY VS. HOT-STRETCH RATIO
FOR 8x1 PET MODEL BRAIDS



MS 2/21/90

TYPE 52 70 DEN, 34 PG
KAWABATA PURE BENDING

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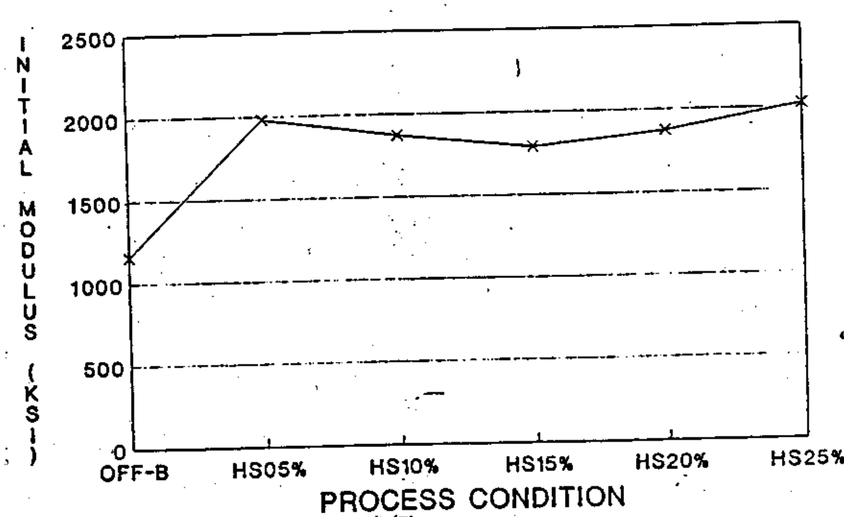
INITIAL MODULUS VS. HOT-STRETCH RATIO
FOR 8x1 PET MODEL BRAIDS



MS 2/21/90

TYPE 52 70 DEN, 34 PG

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002673

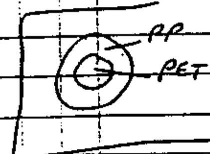
Investigator [signature] Date 2/21/90
Witness [signature] Britt. Date 3-15-90

05
Page
Book No.
2175

Project No. BCF - CBE Experiment No. Date 3/12/90
Subject COMPOSITE BRAID - BCF PP/PET - BICOMPONENT FIBER
Purpose PROCESSING AND PROPERTIES OF PROTOTYPE CONSTRUCTION

BACKGROUND: ONE TYPE OF COMPOSITE BRAID WHICH HAS BEEN EXPLORED INVOLVES THE BLENDING OF 2 FIBER COMPONENTS, ONE WITH HIGH LUBRICITY, AND A SECOND WITH HIGH STRENGTH. THE HIGH LUBRICITY FIBER ACTS AS A SOLID LUBRICANT WHICH ALLOWS EASIER FIBER-FIBER SLIDING WHICH HAS THE NET EFFECT OF IMPROVING PLIABILITY.

EXPERIMENT: A BRAID WAS MADE FROM A PP/PET BICOMPONENT FIBER YARN. THE FIBER WAS APPROX. 50/50 BY VOLUME PP/PET IN A SHEATH-CORE STRUCTURE WITH THE PP IN THE SHEATH.



THE YARN WAS RECEIVED FROM BASF UNDRAWN, WITH A DENIER OF 104. THE YARN WAS SUBSEQUENTLY ORIENTED AT 3.0 X AND 155°F TO PRODUCE A YARN WITH ≈ 4.5 GPD STRENGTH AND 20% STRAIN TO FAILURE. THE YARN (WAS 35 DEN AFTER DRAW) WAS BRAIDED IN A 16x4 CONSTRUCTION AT A 35 PG ON A N.E. BUTT BRAIDER. (WITH NO SPRINGS) THE BRAID WAS SUBSEQUENTLY HOT-STRETCHED AT 5% AND 100°F ON THE "ETHIBOND HOT-PLATE." THE BRAID WAS THEN PLIABILIZED THROUGH A SERIES OF SMALL ROLLERS AT AN INPUT TENSION OF 300 GMS.

RESULTS: THE RESULTING 2-0 BCF BRAID ~~HAD~~ HAD EXCEPTIONAL HANDLING PROPERTIES, FAIR STRENGTH AND KNOT STRENGTH VS SILK AND ETHIBOND. THE RESULTS ARE SUMMARIZED IN THE FOLLOWING PLOTS.

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DISCUSSION: THIS APPROACH DESERVES FURTHER CONSIDERATION, BUT WITH AN IMPROVED YARN WHICH DOES NOT STICK DURING HOT-STRETCHING. A YARN WITH A PROLENE PP POLYMER WILL BE MADE.

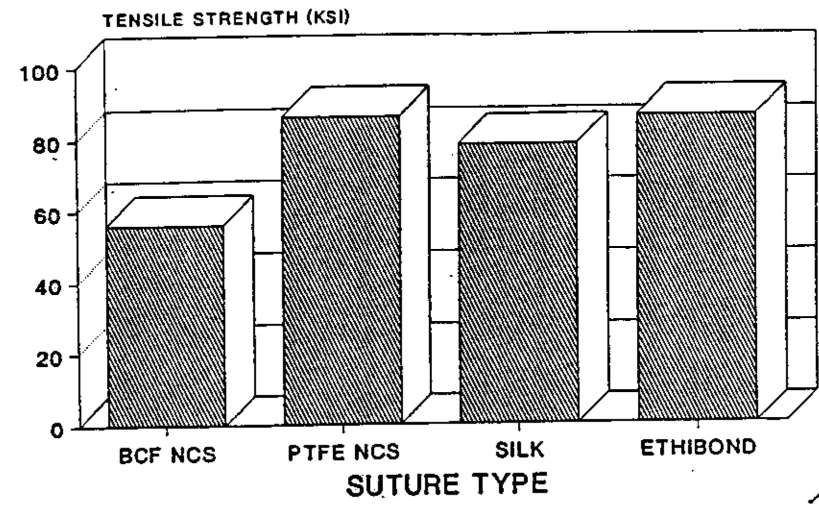
Investigator [signature] Date 3/12/90
Witness Crawford Britt Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002674

Page
Book No.
175

Project No. BCF-CBE Experiment No. Date 3/12/90
Subject Composite Braid
Purpose Continued from p. 65

INTRINSIC STRAIGHT TENSILE STRENGTH FOR PP/PET AND PTFE/PET NCS VS. SILK AND ETHIBOND

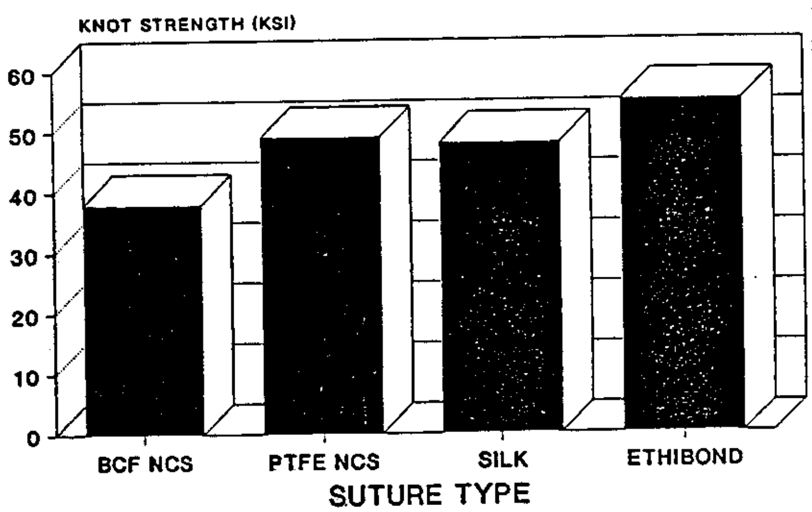


*based on USP diameter
*intrinsic tensile can be size dependent

MS 3/12/90

INTRINSIC KNOT TENSILE STRENGTH FOR PP/PET AND PTFE/PET NCS VS. SILK AND ETHIBOND

MS 3/12/90



*based on USP diameter
*intrinsic tensile can be size dependent

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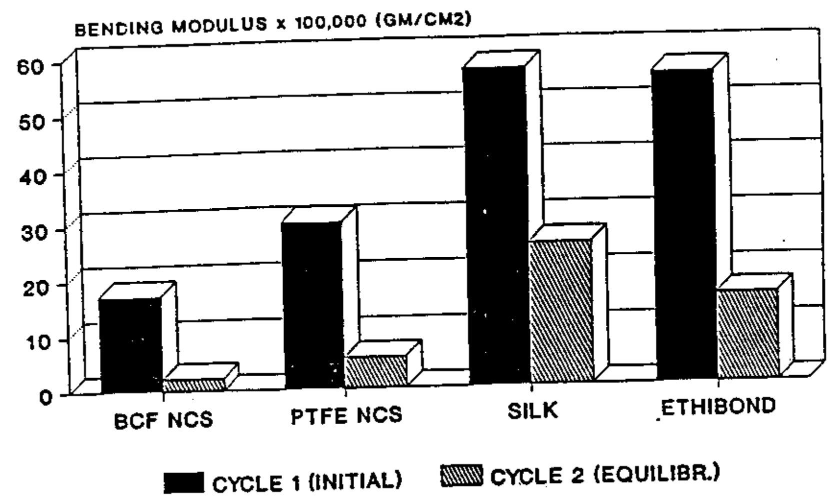
Investigator [signature] Date 3/12/90
Witness [signature] Date 3-15-90

67 Page
Book No. 2175

Project No. BCF-CBE Experiment No. Date 3/12/90
Subject Composite Braid
Purpose Continued from p. 66

PLIABILITY (KAWABATA BENDING MODULUS) FOR PP/PET AND PTFE/PET NCS VS. SILK AND ETHIBOND



NS 3/12/90

$E=(EI)/I$, WHERE; $I=\pi(\text{USP } D)^4/64$

3/12/90
NS

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002676

Investigator [signature] Date 3/12/90
Witness Crawford Britt Date 3-15-90

Page 06
Book No. 2175

Project No. JJO Experiment No. Date 8/30/90
Subject ANNEALING OF AACL DEVICES
Purpose RECORD ANNEALING CONDITIONS

PURPOSE: ANNEAL THE ABSORBABLE ANTERIOR CRUCIATE LIGAMENT DEVICE FOR JJO.

MATERIALS: LOT # PLA-037-11-1
(95/5 PLA/PGA MULTIFILAMENT)

CONDITIONS: OVEN (MICROPROC CONTROLLED - 3RD FLOOR) PER DENNIS JAMIOLKOWSKI

Annealing Scheme For Continuous Loops

Side B

Events: 1 Power on, 2 N_2, 3 Purge, 4 Cooling

Seg No		1	2	3	4	Set Pt.	Time	Recy	Next Seg
		x	x	—	x	25	5 S	—	30
29	Jog	x	x	x	x	25	30 m	—	31
30	Purge	x	x	—	x	$\boxed{95}$	90 m	—	32
31	Ramp	x	x	—	x	$\boxed{95}$	$\boxed{15\ h}$	—	33
32	Maintain	x	x	—	x	25	30 S	—	34
33	Cool to RT_1	x	x	—	x	25	30 S	239	33
34	Cool to RT_2	x	x	—	x	25	2 S	—	$\boxed{40}$
35	Transfer								
40	Cool to RT_3	x	x	—	x	25	30 S	—	41
41	Cool to RT_4	x	x	—	x	25	30 S	239	40
42	Hold	x	x	—	x	25	30 S	—	42
50	Emergency	x	x	—	x	25	5 S	—	50

MS 8/31

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002677

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Investigator [signature] Date 8/30/90
Witness Date

Page

Book No. 2175

Project No. JJO Experiment No. Date 9/7/90

Subject ANNEALING OF AACL

Purpose RECORD ANNEALING CONDITIONS

PURPOSE: SAME AS 2175-68

MATERIALS: 95/5 PLA/PGA MULTIFILAMENT LIGAMENT

LOT # PLA-037-11-1 JJO: 6737-90-10

~~6737-91-10~~

LOT # PLA-037-11-1 6737-90-10

CONDITIONS:

SAME AS 2175-68

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DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI002678

Investigator Date 9/7/90

Witness Date

HERMES DECLARATION
EXHIBIT 8

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

- - -

TRAVEL TRANSCRIPT

DePUY MITEK, INC.,
a Massachusetts corporation,
Plaintiff,

v.

ARTHREX, INC.,
a Delaware corporation,
Defendant.

- - -

WEDNESDAY NOVEMBER 30, 2005

- - -

Oral deposition of DENNIS D. JAMIOLKOWSKI, taken pursuant to Notice, before Jeanne Cahill, RMR, CRR, at the offices of Woodcock Washburn, LLP, One Liberty Place, 33th Floor, 1650 Market Street, Philadelphia, Pennsylvania, commencing at 9:10 a.m.

Page 98

before.
A. I don't believe that I have.
Q. Can you look at the third page of the document where it says Supplemental Response to Interrogatory No. 6?
A. Yes, sir.
Q. Have you seen that response before, either in this form or some other form?
A. I don't believe I have, no.
Q. Could you read the first paragraph of that response?
A. Certainly.
"Supplemental Response to Interrogatory No. 6. Subject to its objections, based on information that is currently in its possession, and with the understanding that its investigation is still ongoing, DePuy Mitek further states that the claimed inventions were conceived at least as early as June 6, 1988, and reduced to practice at least as early as February 2, 1989, at Ethicon, Inc."
Q. You can stop there. I just want to ask you about that sentence.
A. Certainly.
Q. Does Ethicon agree with that sentence?
A. Yes.

Page 99

Q. And is June -- We talked earlier this morning about June 1988 is the document that you've seen that showed work at least as of that date?
A. That's right.
Q. It was June 6, that date, or that document?
A. Yes, sir.
Q. What specifically was conceived as of June 6, 1988?
A. That one could make a braided suture constructed of two or more fiber types designed to realize beneficial properties. The constructions specifically mentioned include PET, polytetrafluoroethylene combinations, PET and polypropylene, and an absorbable construction of PDS and Vicryl.
Four embodiments of this idea include carrier blending, and what that means is that you take the individual yarns that are placed on individual carriers during the construction. And a second method includes where the yarns of the two or more polymers are plied, the plies then resulting on carriers, and then those carriers used to make the braid.
It goes on to describe other ways of making composites, including fiber commingling, and the use of bicomponent fibers.

Page 100

To tell you the truth, I forgot what you asked me.
Q. Well, I asked you what was conceived.
A. And at the very least, that was conceived. And I've taken that off of the first page.
Q. First page of Defendant's Exhibit 35?
A. That is correct.
Q. And that's a document dated June 6, 1988?
A. June 6, '98 correct.
Q. 88?
A. '88.
Q. I caught you that time.
A. What is further conceived or what is further described are various combinations and various proposals for experiments to be done to help evaluate the merits of these ideas.
Q. I want to focus, my question was focused on what was conceived as of that date.
A. Okay.
Q. Now, you mentioned three combinations of materials, correct?
A. There were three combinations that were representative of the ideas, yes.
Q. The third one was the absorbable one?
A. That's correct.

Page 101

Q. And the absorbable one, that's the PDS/Vicryl?
A. That is correct.
Q. And am I correct that the PDS/Vicryl ultimately was not within the claims of the Hunter patent?
MR. BONELLA: Object to the form.
THE WITNESS: I believe that to be the case.
BY MR. SABER:
Q. The PET/PTFE combination, is that within the claims of the Hunter patent?
MR. BONELLA: Object to the form.
THE WITNESS: I believe that to be the case.
BY MR. SABER:
Q. The PET/PP combination, is that within the claims of the Hunter patent?
MR. BONELLA: Object to the form.
THE WITNESS: I believe that to be the case.
BY MR. SABER:
Q. What does PP stand for?
A. Polypropylene.
Q. What does PET stand for?
A. Polyethylene terephthalate.
Q. And what does PTFE stand for?
A. Polytetrafluoroethylene.
Q. And you told me about Vicryl earlier today, but what is PDS?

Page 102

A. PDS is polyparadioxanone. It is an absorbable polyester. It has properties that are different than Vicryl. And it is as a -- it is used as a suture material, and that polymer is also used to make injection-molded implantable absorbable medical devices.

Q. Is the PET/PTFE combination non-absorbable?

A. That is correct.

Q. Is the PET/PP combination non-absorbable?

A. Correct.

Q. As of June 6, 1988, were any other combinations other than -- any other non-absorbable combinations other than PET/PTFE or PET/PP conceived by Ethicon?

A. I believe that the compositions that you mentioned were representative of an idea, which was laid out here. So those were specific embodiments that were mentioned, the idea being the combination of two or more yarns that were selected from different groups.

Q. Were there any specific combinations other than the two represented in Defendant's 35 that had been conceived as of June 6, 1988?

MR. BONELLA: Object to form. Asked and answered.

THE WITNESS: There are none that are recorded in Defendant's 35.

BY MR. SABER:

Page 103

Q. Do you know of any? Does Ethicon know of any as of June 6, 1988, any specific combinations?

A. At the present time, I would say no.

Q. Now, there are four methods of --

A. Right.

Q. -- direct blending, is that the right word, the two yarns?

A. I certainly understand what you mean by that.

Q. Fine. Could you explain what method one is?

A. Certainly.

Q. Called carrier blending?

A. Correct.

In the course of producing a braid, that manufacturing process is easily conducted using a machine called a braider. Examples of this include a Butt braider, B-U-T-T, named after the company, I believe in Massachusetts.

The way this operation works or the way the equipment works is that a plate is provided in which gears are mounted which direct what are called carriers in serpentine fashion. These carriers carry yarn. They're, in fact, in spool form, and the fibers come off the spool.

So what you're doing is you're doing what every mother has done with a child with long hair, in terms of

Page 104

braiding, providing an interconnection between the various yarns.

In the first method, again, called carrier braiding, a carrier will hold a yarn of a given type, let's call it A. Other carriers may contain A as well, but in this setup, at least one of the carriers is required to contain another type of yarn.

So in the diagram that's listed, there is an A and B, and in this case, it is A, A, B, A, A, B, B, indicating that these carriers then have either an A or a B.

Q. Am I correct that on each individual carrier, it's all of A or all of a B?

A. Yes.

Q. The method described in carrier blending, are braids made by that method part of the invention of the '446 patent?

A. Yes.

MR. BONELLA: Object to the form.

BY MR. SABER:

Q. Could you explain the second one?

A. Yes.

Q. Okay. What's called yarn blending.

A. In yarn blending, one would take a yarn, let's say it's A, and take another yarn, and let's say it's B.

Page 105

They would be provided so as to meter out these yarns as supply spools onto another spool. This operation is called plying, P-L-Y-I-N-G.

These yarns can be combined with no twist, with what is called a Z twist, or what is called an S twist, the Z and the S depending upon whether it's right-handed or left-handed.

The subsequent spool containing the plied yarns is then used to supply the carrier spool. So an individual spool may contain a combination of Yarns A and B.

To read from the paperwork, Defendant's 35, yarn blending: "Blending is accomplished prior to the braiding by plying Yarns A and B together to form a composite yarn."

Q. Does that mean that each of the braids on the braider has a combination of A and B plied together?

A. No. You would wind up with only one braid. You used the wrong terminology.

Q. Okay.

A. A carrier may contain --

Q. Let me rephrase the question. Thank you.

A. Please.

Q. Would each carrier have an A and a B plied together?

If you could, on what's marked as Page 8 there, if you could read that last paragraph, and it flops over to the next page, I'm going to ask you a question or two about it.

A. "At least as early as June 6, 1988, the inventors conceived of the idea of a suture having a heterogeneous braid as claimed in the '446 patent.

"For example, Dr. Steckel's laboratory notebook describes the concept of a braided suture constructed of two or more fiber types designed to realize the beneficial properties of each polymer.

"Dr. Steckel's notebook further states that the composites be evaluated using PET/PTFE and PET/PP. As explained, the idea that the PET/PTFE and PET/PP combinations of yarns could be blended by carrier blending or dividing the yarns into two sets, Yarn A residing on one set and Yarn B on the other, having been developed.

"Dr. Steckel's notebook further describes various composite braids that were evaluated. They included a PET/PTFE braid and PET/PP braids that were carrier blended, as noted by CB.

"Dr. Steckel's notebook also describes the construction and evaluation of a braid that was formed with a carrier braider, and a braid of PTFE and PET.

"Documents describing the chronology of the research and development include the documents bearing Bates Nos. DMI 002269-2678 and DMI 002199-2268."

Q. Thank you.

I want to ask you specifically about the sentence that talks about, "Dr. Steckel's notebook further describes various composite braids that were evaluated," and then goes on to say, "These included a PET/PTFE braid and a PET/PP braids that were carrier blended as denoted by CB."

A. Yes, sir.

Q. Looking back at Exhibit 37, the June 6, '88 document that we were discussing before the break, is there any disclosure of a PET/PP braid that was carrier blended as denoted by CB?

A. And the document you wish me to refer to is Document --

Q. Yes, the one that begins on 2617 from exhibit 37, and that entry goes on for four pages.

A. Got it. Okay.

And we're speaking of yarn blending of PET and polypropylene?

Q. Yes, sir. Is that shown in this document, and if so, where?

MR. BONELLA: When you say "document," just to

clarify --

MR. SABER: The four-page June 6 document.

MR. BONELLA: All four pages?

MR. SABER: Yes, sir.

THE WITNESS: So starting with 2617, and CB -- carrier blending or yarn blending?

BY MR. SABER:

Q. Carrier blending. I think you said yarn blending.

A. You said yarn blending.

Q. Did I? I apologize if I did say yarn blending.

A. We don't want to have to take a walk.

Q. I meant to say carrier blending.

A. Okay. On those four pages of DMI 002617 to 2620, there are three carrier blending embodiments that were noted for evaluation, and the combinations were PET and polytetrafluoroethylene.

Q. That's PTFE?

A. PTFE. As well as a Vicryl/PDS combination. So as far as what you asked for PET/polypropylene, they were not part of the initial evaluation package.

Q. Do you know of any support for the statement that the braid -- that Dr. Steckel's notebook describes a combination braid being evaluated of PET/PP by the carrier blended method?

A. I mean, I didn't see it in this document either. Is there anything else that I'm missing?

MR. BONELLA: What document are we talking about?

MR. SABER: The 6/6/88.

MR. BONELLA: The four pages?

MR. SABER: I didn't see it anywhere else, too, by the way, but it's not in the four pages, which is what the interrogatory is referring to.

MR. BONELLA: Object to the form of the question.

THE WITNESS: In terms of being specifically described on those four pages, I do not see any description. However, in the first paragraph of Page 2617, one includes PET/polypropylene combinations. And it's further stated that there are four methodologies that can be employed to combine these different fiber types, and carrier blending is one of the four ways of doing it.

So in terms of reading, on Page 2617, it certainly appears that PET/polypropylene combination by carrier blending is described.

BY MR. SABER:

Q. I understand, but as far as you can tell from this document, does this document ever show that such a

HERMES DECLARATION
EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

Arthrex, Inc., a Delaware
Corporation,

Defendant.
______________________________/

CIVIL ACTION
NO. 04-12457 PBS

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

Q. Let me back up to make sure this is clear. Knot strength versus knot tiedown. In your mind, are they the same thing or are they different?
A. I'm not sure I understand your question. Say that again.
Q. Sure. Knot strength --
A. Mmm-hmm (affirmative).
Q. -- which I think you testified that you understood to be tying a knot in a suture and pulling it on a tensile machine -- tensile tester machine to determine the strength at which the knot will break; right?
A. Yes.
Q. Okay. Then there's another term called knot tiedown, and I'm trying to understand whether, in your mind, you think that's the same as knot strength or do you use that term to mean something else?
A. They're closely related.
Q. And how are they related?
A. When you have a knot tiedown, you've tied a knot. The strength of the knot is going to affect the ability to hold -- to approximate the tissue in the tiedown area that you're talking about.
Q. If the knot had a good tiedown or a bad tiedown, what do you mean by that?

A. Its ability to approximate the tissue and hold it in place through biomechanical forces.
Q. So that's related to knot strength, but it's not necessarily the same thing; is that the way you're using the term?
A. Yes.
Q. The way I heard you describe knot tiedown was you said the ability to approximate the tissue and hold it into place through biomechanical forces.
A. (Witness nods head affirmatively).
Q. When you say ability to approximate the tissue, what do you mean by that?
A. Shift tissue in the position that the surgeon would like for it to be on the bone.
Q. Shift tissue; did you say?
A. Yes.
Q. S-H-I-F-T?
A. Yes.
Q. So the knot's moving the tissue?
A. The suture is holding -- the suture loop with the knot in it, is holding the tissue in the position that the surgeon would like for it to be on bone.
Q. That's taking the place of the tissue? When you say approximate the tissue, how is it approximating tissue?

A. It's -- The tissue is here. The location the surgeon wants it here. The suture loop as it is tied moves the tissue into position.
Q. Holds it there?
A. Yes.
Q. And what -- what biomechanical forces were you referring to?
A. Forces on the glenohumeral joint.
Q. In a knot strength test, it's the forces are being applied and generally in one direction; correct?
A. Yes.
Q. The biomechanical force that you are referring to in this knot tiedown, the forces are coming from different directions; right?
A. Yes.
Q. Okay. When you are referring to knot tiedown then, you're referring to -- you're referring to it in a sense as a strength?
A. Are you finished? Is that the question?
Q. Right.
A. I don't believe -- Say it again then.
Q. Sure. Knot tiedown, the way you're referring to it, it's a strength then? It's kind of like -- because knot strength would be measured in p.s.i.
A. I said that's one of the attributes of it.

That's not the total attribute of it. I mean it's to approximate tissue into position is knot tiedown.
Q. Well, what else would be included?
A. I just told you. Approximate tissue, strength.
Q. So the strength would -- I understand the --
A. The size of the knot bundle. You know, there's --
Q. Size of the knot bundle?
A. Yes.
Q. What do you mean by that?
A. How large the knot is once it has been tied and cut.
Q. So knot tiedown includes the size of the knot bundle?
A. Yes. You know, the knot tiedown -- I want to say this -- that's not a term that we specifically use, so it's a little bit foreign. I mean I don't -- I've never had a surgeon ask me about knot tiedown.
Q. Okay.
A. So I didn't -- your -- I'm not sure where you're going with this, but there's -- we did knot testing and we did straight pull testing of the suture so that your knot tiedown, I'm -- I'm not real sure what you're asking for there. I --
Q. Well --

30

A. I said they are related.
Q. Okay. They're your terms. I just want to understand them because when we ask questions, I want to make sure we're both on the same page, because there's a lot of terms that we're throwing around, and some people have different definitions and some people have different understandings of what they mean, so I want to know that when I ask you a question and I ask you a question about knot tiedown that we're both talking about the same thing so there's no misunderstanding what we're talking about.
A. I've told you they were closely related.
Q. Right. But closely related doesn't tell me what knot tiedown is in your mind, so I'm trying to figure out what it means in your mind. So now I've heard you say that it's the ability to approximate the tissue and hold it in place through biomechanical forces?
A. (Witness nods head affirmatively).
Q. I heard you say the size of the knot bundle is part of knot tiedown?
A. (Witness nods head affirmatively).
Q. And by size of the knot bundle, you are referring to how big the knot is when it's tied?
A. Correct.
Q. Anything else included within knot tiedown in your mind?

31

A. Not that I can think of right now.
Q. Okay. So in evaluating the Tevdek suture, did you evaluate the Tevdek suture for knot tiedown characteristics?
A. Evaluated for knot strength and straight pull.
Q. How about knot tiedown characteristics?
A. There is no test report that would have knot tiedown as -- as part of the characteristics that were tested.
Q. You said there's no test report. And my question -- that does not necessarily answer the question.
MR. SOFFEN: I think he answered it no at the beginning of the answer.
Q. That's not what the record says.
A. I told you it was a term that we didn't use directly. Knot tiedown -- "knot tiedown" was not used. So the answer to your question then is no.
Q. No? Okay. How about the Pearsalls suture that was polyester? Was that evaluated for knot tiedown characteristics?
A. No.
Q. Okay. How about the term "knot security"? Are you familiar with that term?
A. Yes.
Q. What does knot security mean to you?

32

A. The ability of the knot to not slip and to maintain the inner loop linear section that was tied with the knot and hold -- and maintain that during biomechanical forces without slippage.
Q. What do you mean by the inner loop linear section of the knot?
A. When you tie a knot, you're tying it most of the time to bone and tissue. There's -- If you tie a knot, then there's a loop; okay? The knot slippage would be measured as an increase in that loop diameter.
Q. Is there a standard test for that?
A. What do you mean standard test?
Q. A test -- Well, let me rephrase the question.
A. Is there any test for it? Or I don't understand the question.
Q. Let me rephrase the question. Was there a test that you are familiar with that you generally used to evaluate knot security?
A. Not generally. It was tested, but -- but not every time.
Q. And what test was that?
A. There -- the -- What test?
Q. Right.
A. The test for the slippage of the knot.
Q. And how was that test conducted?

33

A. Pull tested with the inside i.d. of the suture held and measured the strength before the increase in size of the inner loop.
Q. What type of machine was used for that?
A. Tensile test machine.
Q. Would you draw a picture of that test.
A. (Witness complying).
Q. Okay. Can you label the components you've drawn.
A. (Witness complying).
Q. And can you describe what you have labeled -- I see you have labeled the crosshead, two hooks, the knot, and a suture loop; right?
A. Yes.
Q. Okay. And the forces applied by -- Well, what type of machine is this? I'm sorry. This is a tensile test?
A. Tensile test.
Q. And force is applied to pull from each direction, top and bottom, if you will?
A. That's what the two arrows signify.
Q. Okay. Are there mandrels which that knot -- around that suture loop? Does the suture loop go around mandrels?
A. Hooks or pins or some way to affix the suture. So when you say a mandrel, I mean there's a lot of

34

different types of mandrels.
Q. Okay.
A. I'm not sure what you mean.
Q. Something with a hook that the loop wraps around, goes around -- the suture loop goes around?
A. I've got two hooks listed there, yes.
Q. Okay. And you labeled the knot; right?
A. Yes.
Q. And this test is measuring -- Can you explain to me how this test is measuring --
A. Yeah, once the crosshead moves --
Q. Right.
A. -- this is placed under a fixed tension to start with to remove any -- any slack in the loop --
Q. Correct. Okay.
A. -- and then once it's test -- once the crosshead is moved, you measure the tensile strength which is required to increase that loop opening.
Q. Are you pulling on one of the parts of the knot?
A. That's what -- What do you mean parts of the knot? No. The knot's here on the side. Pulling 90 degrees from the knot on both ends.
Here, I'll draw you a bigger picture.
Q. Thank you.
A. (Witness complying).

35

Q. Well, the knot that you're describing here, is this knot the same knot as, for example, that you would tie your shoe? You just go over?
A. It's a square knot.
Q. You're calling it a square knot? Okay.
A. Yes. Now you can tie many different knots there.
Q. Right.
A. To determine which knot has the best efficiency with use with that particular type of suture -- there's 30 or 40 different types of knots.
Q. Okay.
A. The test calls for a square knot.
Q. Okay. And when the force is applied, it's measuring -- you want it -- the object here is to determine how much -- or I'm sorry -- the object is to determine when the suture that's tied in this knot starts slipping out of the knot?
A. Yes.
Q. And the force at which it does that is considered the knot -- it's the knot security?
A. Yes.
Q. Okay. Did you analyze the Pearsalls polyester suture for knot security?
A. Yes.
Q. How about the Tevdek suture? Did you analyze

36

that for knot security?
A. Yes.
Q. Okay. So in selecting sutures in your experience, knot security, knot strength, tensile strength are all important considerations?
A. Yes.
MR. SOFFEN: Are you going to label that as an exhibit?
MR. BONELLA: Sure. If you would date that and initial that, Mr. Grafton.
We'll mark that as DePuy Mitek Exhibit 421. And that's Mr. Grafton's drawing of the knot security test.
(DePuy Mitek Exhibit No. 421, Mr. Grafton's drawing of the knot security test, was marked for identification.)
Q. The Tevdek suture, was that also polyester?
A. Yes.
Q. And Size 2?
A. Yes.
Q. Any other sizes?
A. Possibly.
Q. But you don't remember?
A. No.
Q. Was the Tevdek suture braided?

37

A. Yes.
Q. Did the Tevdek suture have a core?
A. I have no idea.
Q. Why was there a shift -- Let me back up. When Arthrex began selling the Tevdek polyester suture, did it stop selling the Pearsalls polyester suture?
A. Yes.
Q. Why was there a shift from the Pearsalls polyester suture to the Tevdek polyester suture?
A. I answered that question already.
Q. You did? I'm sorry. I missed it. What was the reason?
A. The stiffness and compliance of the suture.
Q. So the Tevdek suture was more compliant --
A. That's correct.
Q. Let me finish the question. The Tevdek suture was more compliant than the Pearsalls polyester suture?
A. That's correct.
Q. Did the Tevdek suture have a coating?
A. Yes.
Q. Do you know what the coating was?
A. No.
Q. And the Pearsalls suture, was the braid constructed on a carrier braider machine?
A. Yes.

42

A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they

43

compared to the competitive products.
Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength

44

and tensile strength; right?
A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr.

45

Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."
And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is

processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had

this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes.
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent. I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

54

MR. SOFFEN: Objection; asked and answered. You've asked him the same thing multiple times. But you can answer.
A. I've lost count, it's been so many times, but the answer again is yes.
Q. Okay. And Dr. Burkhart said that was a killer idea?
A. What was a killer idea?
Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question.
Did Dr. Burkhart say that your idea to braid PET with the ultra-high molecular weight polyethylene to improve knot security was a killer idea?
A. Yes.
Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra-high molecular weight polyethylene braided?
A. Yes.
Q. And you tested that prototype?
A. Yes.
Q. And you said that that prototype had good knot strength?
A. Correct.
Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

55

A. Yes.
Q. And the prototype of PET and ultra-high molecular weight polyethylene braided together also had good tensile strength?
A. Yes.
Q. And after you tested this second prototype, if you will, of the PET braided with ultra-high molecular weight polyethylene, was then the decision made to pursue trying to commercially develop this idea?
A. Yes.
Q. Did you -- when you made -- Who made the decision to go forward and try to commercialize this idea?
A. Myself and Reinhold, surgeons that we collaborated with, marketing people. You know, it wasn't just myself.
Q. Okay. Was this prototype that had the PET braided with the ultra-high molecular weight polyethylene, was it -- did it have a coating on it?
A. Yes.
Q. It did?
A. (Witness nods head affirmatively).
Q. And what was the coating?
A. I forget the name. It's like an MED2174s.
Q. That was on the prototype?
A. Which prototype are you referring to now?

56

Q. I'm talking about the --
A. The second prototype with the PET?
Q. Correct.
A. Yes.
Q. The second prototype that had the coating on it?
A. Yes.
Q. And was that part of your initial idea, or was that -- because I thought you said your initial idea was to add the PET. Was it also to coat it, or was that something that came later?
A. If you're going to market the product, it needs the coating on it, sir.
Q. Okay. But the prototype that was manufactured that you asked --
A. Most likely, it was coated, because it needed to be as the final product would be marketed.
Q. You said most likely. Do you remember or you don't remember whether the prototype that had the PET and the ultra-high molecular weight polyethylene was coated?
A. I can't tell you for sure that it was at that prototype stage.
Q. Okay. Was this prototype that you had -- after you tested the prototype with PET with ultra-high --
A. Excuse me. I want to change that.
Q. Okay.

57

A. I never got samples of constructions from Pearsalls without a coating unless I specifically asked for it not to be coated. So there's a very high probability that the suture came as -- the second prototype -- as coated.
Q. That was standard for them to coat it, in other words?
A. Yes.
Q. Okay. So the initial prototype that was ultra-high molecular weight polyethylene, did you ask for that not to be coated?
A. No.
Q. So chances are that that one was coated?
A. Quite possibly.
Q. After you tested the prototype of PET and ultra-high molecular weight polyethylene braided together, did you believe that it would then work as a suture?
A. Yes.
Q. Okay. Is there anything else you think you needed to do in order to determine whether it would work as a suture?
A. Yes.
Q. What did you need to do?
A. Biocompatibility toxicity testing, bioburden levels, all the design control GNP items that need to be

done on any product. Obviously, there needed to be a check -- there's a checklist -- okay -- so I'm going by memory, that it needed to be looked at from a patent standpoint to see if there was any infringing as well as whether the product was compatible, along with the GNP items that are required for the product.
Q. Okay. Those things you are describing to me, those were all kind of commercial considerations. My question is a little different. Maybe my question wasn't clear. My question was more along the lines of once you had the prototype of the ultra-high molecular weight polyethylene and PET braided together and you tested it and you believed that it would work as a suture, I understand there's things you needed to do to make it a commercial product.
Was there anything else you needed to do in your mind to clarify whether it needed to -- whether it could work as a suture?
A. We needed to have a surgeon look at it that would actually be tying knots with it to get their understanding of -- of how they felt about the suture.
Q. Okay. Anything else though?
A. Not that I recall.
Q. Okay.
MR. SOFFEN: Is it time for a break? In a few

minutes?
MR. BONELLA: Yeah. Just give me five. Let me just finish this line of questions.
Q. Was the initial prototype that was ultra-high molecular weight polyethylene, was that sterile?
A. I don't remember.
Q. How about the prototype that was PET and ultra-high molecular weight polyethylene braided together? Was that sterile?
A. I don't remember.
Q. Would it have to have been sterile? Would the prototypes have to have been sterile?
A. Not to test on the tensile test machine.
Q. Why not?
A. Because it's not going into a human. You don't -- The bioburden levels at that point is not a factor that was wrong.
Q. Was sterilization another process at that time? Was that something you really didn't have to account for?
A. Say the question again.
Q. I'm just making sure that what you're saying is that sterilization is just to -- was just to -- it's really for biocompatibility? It's not to change the properties of the material; is that right?
MR. SOFFEN: Objection; vague.

A. I don't know. I don't know. That's really a weird question.
Q. I understand you are saying they weren't sterile.
A. No. I didn't say -- I said I don't recall, sir.
Q. You don't recall?
A. Yes.
Q. Okay. And my question was would they have had to have been, and you said, I think, no because they were testing them for mechanical properties.
A. Yes.
Q. Okay. Did you -- Would the sutures have had to have been sterile when you tested them for mechanical properties?
A. I already answered that.
MR. SOFFEN: Objection; asked and answered.
A. I said no. It didn't have to be to be tested on a tensile test machine.
Q. And why is that?
A. I already answered that also. It's not being used for human or animal use, so the biocompatibility issues of the suture at that time were not looked at. The mechanical features of the suture were all that were looked at at that portion of the prototype stage.
Q. Did sterilization have a big effect on the mechanical properties of the suture, the tensile?

MR. SOFFEN: Objection.
A. I -- I can't answer that question.
Q. You don't know?
A. No.
Q. But when you made the decision to go forward with this, you can't remember whether they were sterile or not?
A. You asked me -- You're -- you're kind of putting a couple of things together, so that's why you're --
Q. Okay. Maybe I'm getting confused.
A. You asked me if the prototypes were sterile, and I said no.
Q. Okay.
A. The decision to go forward with the product, obviously, there has to be sterilization done before the product can be marketed.
Q. Absolutely. And are you saying that the decision to go forward with it was made before you tested a sterile product?
A. I can't say that.
Q. Do you recall testing a sterile product before the decision was decided to make -- decided to go forward with the PET and the --
A. I don't remember.
Q. -- ultra-high molecular weight polyethylene?
A. I don't -- It depends on what point in time you

94

A. I don't recognize this particular exhibit, but it looks like a test report.
Q. Is that your signature on the first page?
A. Yes, it is.
Q. And you signed it on February 13th, 2003?
A. Right.
Q. And the test objective stated was to evaluate US -- I'm sorry -- FiberWire US 3/4 sutures, construction numbers DTPS 21 and DTPS 34 for knot pull, straight pull, and diameter. Do you see that?
A. Yes.
Q. And the previous exhibit, 175, refers to DTPS 21 and 34 and that was in January of '03; right?
A. Yes.
Q. Okay. Looking at Exhibit 422, does that refresh your memory at all as to why Arthrex was evaluating a 100 percent polyester -- I'm sorry. I will rephrase the question.
Looking at Exhibit 422, does that refresh your memory at all as to why Arthrex was evaluating a construct that had 100 percent polyester in the sheath?
A. I don't remember.
Q. You don't remember? In the Observations and Conclusions section of Exhibit 422 on the front, it said, "Also, both the sutures had similar strength in straight

95

pull, but knot pull const. DTPS 34 had more strength than DTPS 21. Hence, only construction DTPS 34 is approved for production." Do you see that?
A. Yes.
Q. Do you recall reaching that conclusion?
MR. SOFFEN: Objection. There's no evidence that it's Mr. Grafton's conclusion here, but ...
MR. BONELLA: It's coming.
A. I don't remember the circumstances of this document, so I can't really answer that.
Q. Would you turn to Page ARM 25664.
A. Is that in this document?
Q. Yes. In Exhibit 422. Do you see it's a Pearsalls Limited Certificate of Conformity?
A. Yes.
Q. Do you see that?
A. Yes.
Q. Do you recall seeing these types of documents before from Pearsalls?
A. Yes.
Q. What was your understanding of the purpose of a Certificate of Conformity that Pearsalls would send?
A. It's a cert that goes with the product to give the certifications of how it was tested and what the conformance of it is.

96

Q. And that's according -- and those certs are according to the U.S. Pharmacopeia?
A. Yes.
Q. Now does Pearsalls sterilize the products for Arthrex?
A. No.
Q. So these Certificates of Conformity are issued without sterilization?
A. That's correct. In this particular one, yes.
Q. In general, were the Pearsalls --
A. In general, Pearsalls, yes. That was -- that was prior to sterilization when we received the product from Pearsalls.
Q. Did Arthrex do a new Certificate of Conformity after the products have been sterilized?
A. It was tested after sterilization.
Q. Does Arthrex do a new Certificate of Conformity?
A. There was quality control records that would show the test result after sterilization.
Q. And how were those tests -- how were those tests done?
A. Same type of tests, knot, straight pull.
Q. Okay. And were they done for each batch of FiberWire, or did you select a certain sample from each batch? Like how were the tests done after sterilization?

97

A. Early on, I'm sure every batch was done. After that, probably not every batch.
Q. Do you recall the results of those tests?
A. No.
Q. What type of sterilization procedure does Arthrex use for FiberWire?
A. ETO and gamma.
Q. And those are known procedures? Are they -- I will ask a better question.
Did Arthrex develop those procedures, the sterilization of ETO and gamma, or were those known procedures in the art?
A. What do you mean by known? ETO and gamma are sterilization methods used in medical products. If that's your definition of known, the answer to that is yes.
Q. Did Arthrex develop anything special about applying those techniques to FiberWire?
A. They depended on how the product was sold. Whether it was sold in an envelope or with a suture anchor, there would be different types of sterilization that Arthrex would have been involved in the development.
Q. What do you mean by depending upon the -- how the product was sold?
A. Whether it was sold with a suture anchor, metal or bioabsorbable, those require different types of

146

uncoated but that had gone through the scouring and dye process?
A. I don't remember.
Q. When you tested the coated versus uncoated, do you know whether the coated one that you tested was one that had been dyed --
A. I don't remember that.
Q. -- or undyed? Okay. If it's a -- Okay. Do you recall like any invoices that came back with the samples that you asked for for testing in relation to the Ethicon patent?
A. No. There may not have been invoices.
Q. Do you see inside these packages, there's -- it looks like, at least for this one --
A. Ah, okay. Here. You see this little round section?
Q. Yes.
A. This is most likely the information that was on the round 2-inch spool.
Q. Okay.
A. And this is where somebody xeroxed it on the machine, it looks like, and cut it out, the silhouette of it, and that's what we're looking at there, now that I see it closer.
Q. Okay. Do you see where it says batch? Coated

147

MED. At least this one says Coated MED. And it says Batch on it. And it's Exhibit 428.
A. I see the information, yes.
Q. Okay. Do you see the uncoated one has a -- it has a batch number there. Do you see that for the uncoated?
A. Yes.
Q. Is that a Pearsalls batch number?
A. Yes.
Q. And do you see the other number there? There's a -- on the -- it has the number 38A500500? Do you see that number?
A. Yes.
Q. Do you recognize that number?
A. No. It's not an Arthrex number.
Q. Okay. How about the L51211 number? Do you recognize that number?
A. No. Those are all Pearsalls' internal numbers.
Q. Okay. Did you keep any records of the samples that you got from Pearsalls for testing uncoated versus uncoated with respect to the 44 -- with respect to the Ethicon patent of how the samples were to be maintained or kept?
A. I'm sure I turned the samples over to our test group. I don't recall any -- and probably any certs or

148

information that were with them, but I didn't keep any of that.
Q. Okay. When you say you turned them over to the test group, do you mean when you left or was that when you completed the coated versus uncoated testing that you did?
A. At the time that the testing was to be done, I would give them the samples and the certifications so they would know which is coated and which is uncoated.
Q. Okay. And did you get the samples back after the testing, or did they remain with the test group?
A. I don't remember.
Q. Okay. I think the question kind of came out fuzzy. I have to reask one of the questions. I misspoke.
Did you keep any records of the samples that you got from Pearsalls for testing coated versus uncoated with respect to the Ethicon patent?
A. Keep any copies of the records?
Q. Yeah.
A. The test results?
Q. No, the records in terms of maintaining the samples, of how the samples were to be maintained or --
A. I turned all of that over to the test department.
Q. Okay.
A. Because they would need that to be able to write up the test report, any information I had.

149

Q. Do you know if any of the samples that -- when you tested the coated versus uncoated in relation to the testing for the Ethicon patent, had any of those undergone sterilization?
A. I don't think they had.
Q. Okay. Now in the coating process that Pearsalls uses, there's an oven, and there's some tension applied during that process?
A. Yes.
Q. Right? Do you know if the uncoated sample that you tested in relation to the Ethicon patent had undergone that heat process and the tensioning?
A. They both -- The coated or both?
Q. No, the uncoated.
A. Uncoated?
Q. Right.
A. I'm sure it did not.
Q. Okay.
A. When you are saying heat process, it's to flash off the solvents with -- with the amount of heat is used for.
Q. Are you aware of the temperatures that are used?
A. No.
Q. Are you aware of how long the FiberWire is in the ovens?

150

A. I have seen their equipment, and it's approximately a 50-foot long zoned oven.
Q. Do you know how fast the FiberWire is moving through there?
A. I -- At one time, I had that information, but I don't recall what it is now, how many feet per minute went through.
Q. Have you ever done any analysis as to whether that heating process and the -- whatever tension is applied has any effect on the material properties of the suture?
A. Well, it's hard to separate that from the coating, because the coating is -- what you're trying to accomplish there is put the coating on it which increases the lubricity of the product.
Q. Right.
A. So that that's not separated.
Q. Okay. Now the tests that you did or that you -- well, what was -- There was a test done in relation to this Ethicon patent of a coated versus an uncoated sample; right?
A. Yes.
Q. Do you recall that test?
A. To some extent. I know the people that worked on it.

151

Q. Okay. Did you personally witness the test?
A. I think I went back there a couple of times, but I don't remember the test that well.
Q. Okay. I just wanted to know whether you -- not necessarily whether you remember the test, but whether you personally witnessed it being done or you just kind of saw the results?
A. Well, it was over a long period of time, and I was in and out of the test lab.
Q. Okay.
A. So I did not witness the total time that the suture was being tested.
Q. What do you mean by over a long period of time?
A. A couple of days. It takes a while to set up fixtures and get the test working so that you can see the results.
Q. Okay. The testing that you saw --
A. It was a new test that we had never done before, so it's -- you know -- it takes a while to be able to get your test set up correctly.
Q. Okay. So you were involved in designing the test?
A. Ashley -- to some extent. I think Ashley and James Thomas were probably the two that were more involved with it.

152

Q. Okay. And --
A. I was more involved with determining the test samples and what we were looking for as a theorem at that time to -- to determine the difference between the two.
Q. And what were you -- what were you looking for? What was the theorem?
A. That adding the coating increased the lubricity of the suture.
Q. Okay. And so you -- You were involved to some extent in helping them to design this test to prove that point?
A. I explained that already. I was involved in providing the samples --
Q. Okay.
A. -- and what we were looking for. And how it was set up -- you know -- I don't recall any specific things that I told them to do there.
Q. Okay. So did you -- so did you approve the test --
A. Yes.
Q. -- before it was conducted?
A. Yes.
Q. Okay. And then you looked at the results afterwards?
A. Yes.

153

Q. And what did you conclude from the results?
A. That the coated suture increased the lubricity of the suture.
Q. Okay. And did you convey that to Mr. Soffen?
A. Yes.
Q. Did you convey any other results to Mr. Soffen in this testing of the coated versus uncoated samples?
A. I don't recall.
Q. Okay. How about Mr. John Schmieding? Did you convey to him the results?
A. I'm sure he was -- knew the results also.
Q. And the results being that the lubricity of the coating affected the lubricity of the product?
A. Increased the lubricity.
Q. Increased the lubricity. Okay.
Now you said the hypothesis or theorem was to test for coating effects? Is that -- Am I saying that right? I'm not trying to put words in your mouth. I'm just trying to set up a foundation for the next question.
A. To see if there was a difference.
Q. Okay.
A. And to be able to measure the difference.
Q. Okay. And who -- whose idea was it to do that?
A. I don't recall.
Q. Okay. Do you know -- Did Mr. Soffen tell you

HERMES DECLARATION
EXHIBIT 10

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D. K. DANDGE
New Mexico Institute of Mining and Technology

L. G. DONARUMA
University of Alabama in Huntsville

NOMENCLATURE

Nomenclature, as used in this article, refers to the naming of polymeric materials. The nomenclature of scientific communication is emphasized, although there is generally little reason for differences between scientific and other, eg, commercial, usage.

Since the publication of the first edition of this Encyclopedia, the International Union of Pure and Applied Chemistry (IUPAC) has established the Commission on Macromolecular Nomenclature, which is now the leading nomenclature body in the polymer field. The Commission is promulgating a series of rules and definitions that are placing polymer nomenclature on a much more systematic basis than had previously been the case (Table 1) (1–21). The International Standardization Organization (ISO), primarily through its Technical Committee TC/61 Plastics, and various national nomenclature bodies (such as that of the American Chemical Society) are also helping to shape the field. Recent issues of *Chemical Abstracts* are additional authoritative sources of polymer nomenclature.

At the present time, the IUPAC Commission on Macromolecular Nomenclature is developing a set of definitions for many of the basic terms dealing with polymer molecules, assemblies of polymer molecules, polymer solutions, polymer crystals, polymer melts and solids, polymerization reactions, etc. It is also extending existing nomenclature to more complicated cases, such as cross-linked polymers. When this phase of the work is completed by the late 1980s, the naming of polymers and polymer terminology will have become largely systematized and, following the IUPAC practice in other fields of chemistry, a compendium of polymer nomenclature rules will be published.

Table 1. IUPAC Publications on Polymer Nomenclature

Title	Comment	Refs.
Report on Nomenclature in the Field of Macromolecules	obsolete	1
Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 2	3
Revised Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 4	2,5
Report of the Committee on Nomenclature of the International Commission on Macromolecules	obsolete	6
Basic Definitions of Terms Relating to Polymers		7,8
List of Standard Abbreviations (Symbols) for Synthetic Polymers and Polymer Materials (1974)	superseded by Ref. 9	10
Use of Abbreviations for Names of Polymeric Substances	Recommendations 1986	9
Nomenclature of Regular Single-Strand Organic Polymers		11
Stereochemical Definitions and Notations Relating to Polymers	Provisional Recommendations 1980	12 4
Nomenclature for Regular Single-Strand and Quasi Single-Strand Inorganic and Coordination Polymers	Provisional Recommendations 1984	13 14
Note on the Terminology for Molar Masses in Polymer Science		15–17
Source-Based Nomenclature for Copolymers		18
Definitions of Terms Relating to Individual Macromolecules, Their Assemblies, and Dilute Polymer Solutions		19
Definitions of Terms Relating to Crystalline Polymers		20
A Classification of Linear Single-Strand Polymers		21

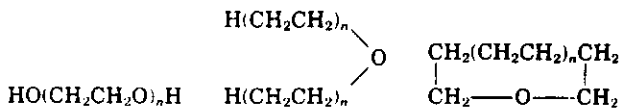
Basic Definitions

No nomenclature document is more fundamental to a given science than the definitions of basic terms used in that area. The IUPAC Commission on Macromolecular Nomenclature published a document in 1974 (8) that offers definitions of 52 terms, including polymer, constitutional unit, monomer, polymerization, regular polymer, tactic polymer, block polymer, graft polymer, monomeric unit, degree of polymerization, addition polymerization, condensation polymerization, homopolymer, copolymer, bipolymer, terpolymer, copolymerization, and many others. Both structure-based and process-based definitions are given.

Source-based Nomenclature

Traditionally, polymers have been named by attaching the prefix poly to the name of the real or assumed monomer (the "source") from which it is derived.

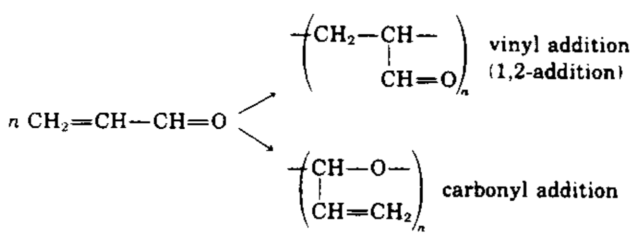
Thus polystyrene is the polymer made from styrene and will often be found in an index under "styrene, polymer of." When the name of the monomer consists of two or more words, parentheses should be used (1), as in poly(vinyl acetate), poly(methyl methacrylate), poly(sodium styrenesulfonate), etc. Failure to use parentheses can lead to ambiguity: polychlorostyrene can be the name of either a polychlorinated (monomeric) styrene molecule or a polymer derived from chlorostyrene; polyethylene oxide can refer to polymer (**1**), polymer (**2**), or the macrocycle (**3**).



(**1**) (**2**) (**3**)

These problems are easily overcome with parentheses; names such as poly(chloro)styrene, poly(chlorostyrene), and poly(ethylene oxide) clearly indicate the part of the name to which the prefix poly refers. The omission of parentheses is, unfortunately, quite common.

The principal deficiency of source-based nomenclature is that the chemical structure of the monomeric unit in a polymer is not identical with that of the monomer, eg, $—CH_2—CHX—$ vs $CH_2{=}CHX$; thus the name polymonomer is actually a misnomer. The structure of the repeating unit is also not specified in this scheme; for example, polyacrolein does not indicate whether the vinyl or the aldehyde group has polymerized (see ACROLEIN POLYMERS).



Different types of polymerization can take place with many other monomers, depending on the polymerization conditions. Furthermore, a name such as poly(vinyl alcohol) refers to a hypothetical source, since this polymer is obtained by hydrolysis of poly(vinyl acetate). In spite of these serious deficiencies, source-based nomenclature is still firmly entrenched in industrial literature and, to a lesser extent, in scientific communication. It originated at a time when polymer science was less developed and the structure of most polymers ill-defined. The rapid advances now being made in structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from starting materials and toward the structure of the macromolecules.

Copolymers. Copolymers are polymers that are derived from more than one species of monomer (8). Because this is a process-based definition, source-based nomenclature can be easily adapted to the naming of copolymers (18). However, the arrangement of the various types of monomeric units must be specified. Seven types of arrangements have been defined and are shown in Table 2, where A, B, and C represent the names of monomers. The monomer names are linked through a connective (infix), such as *-co-*, to form the name of the copolymer, as in poly(styrene-*co*-acrylonitrile). The order of citation of the mono-

mers is arbitrary, except for graft copolymers where the backbone monomer is named first.

An equally acceptable alternative scheme utilizes the prefix copoly followed by citation of the names of the monomers used, separated from each other by an oblique stroke. Parentheses are also needed. For example, copoly(styrene/butadiene) denotes an unspecified copolymer of styrene and butadiene. The other connectives of Table 2 are placed before such names to provide additional structural information, as in

stat-copoly(styrene/butadiene)
ran-copoly(ethylene/vinyl acetate)
alt-copoly(styrene/maleic anhydride)
per-copoly(ethylene phenylphosphonite/methyl acrylate/carbon dioxide)
block-copoly(styrene/butadiene/methyl methacrylate)
graft-copoly(styrene/butadiene)

It is not necessary to use parentheses to enclose vinyl acetate, maleic anhydride, methyl acrylate, etc, even though the name of each of these monomers consists of two words; the names of the polymers, as written here, are unambiguous.

The names of copolymers, derived either from the main scheme or the alternative, can be further modified to indicate various structural features. For example, the chemical nature of end groups can be specified as follows:

α-X-ω-Y-poly(A-*alt*-B)
α-butyl-ω-carboxy-*block*-copoly(styrene/butadiene)

Whereas subscripts placed immediately after the name of the monomer or the block designate the degree of polymerization or repetition, mass and mole fractions and molar masses, which in most cases are average quantities, are expressed by placing corresponding figures after the complete name of the copolymer. The order of citation is as for the monomeric species in the name. Unknown quantities are designated by a, b, etc. Some examples follow.

A block copolymer containing 75 mass % of polybutadiene and 25 mass % of polystyrene is

polybutadiene-*block*-polystyrene (0.75:0.25 w) or
block-copoly(butadiene/styrene) (75:25 mass %)

A graft copolymer, consisting of a polyisoprene backbone grafted with isoprene and acrylonitrile units in an unspecified arrangement, containing 85 mol % of isoprene units and 15 mol % of acrylonitrile units is

polyisoprene-*graft*-poly(isoprene-*co*-acrylonitrile) (0.85:0.15 x) or
graft-copoly[isoprene/(isoprene;acrylonitrile)] (85:15 mol %)

A graft copolymer consisting of 75 mass % of polybutadiene with a relative molecular mass of 90,000 as the backbone and 25 mass % of polystyrene in grafted chains with a relative molecular mass of 30,000 would be

polybutadiene-*graft*-polystyrene (75:25 mass %; 90,000:30,000 M_r)

Table 2. IUPAC Nomenclature of Copolymers[a]

Type	Arrangement of monomeric units	Structure	Connective	Example
unspecified	unknown or unspecified	(A-*co*-B)	-*co*-	poly[styrene-*co*-(methyl methacrylate)]
statistical	obeys known statistical laws	(A-*stat*-B)	-*stat*-	poly(styrene-*stat*-acrylonitrile-*stat*-butadiene)
random	obeys Bernoullian statistics	(A-*ran*-B)	-*ran*-	poly[ethylene-*ran*-(vinyl acetate)]
alternating	alternating sequence	$(AB)_n$	-*alt*-	poly[(ethylene glycol)-*alt*-(terephthalic acid)]
periodic	periodic with respect to at least three monomeric units	$(ABC)_n$ $(ABB)_n$ $(AABB)_n$ $(ABAC)_n$	-*per*-	poly[formaldehyde-*per*-(ethylene oxide)-*per*-(ethylene oxide)]
block	linear arrangement of blocks	—AAAAA—BBBBBB—	-*block*-[b]	polystyrene-*block*-polybutadiene
graft	polymeric side chain different from main chain[c]	—AAAAAAAAAAAA— B B B B B	-*graft*-[d]	polybutadiene-*graft*-polystyrene

[a] Main system of the IUPAC document (18); an alternative scheme is described in the text.
[b] The connective -*b*- has also been used.
[c] Main chain (or backbone) is specified first in the name.
[d] The connective -*g*- has also been used.

A graft copolymer in which the polybutadiene backbone has a DP of 1700 and the polystyrene grafts have an unknown DP is named

graft-copoly(butadiene/styrene) (1700:*a* DP)

The published IUPAC copolymer document (18) should be consulted for the names of more complex copolymers, eg, those having a multiplicity of grafts or having chains radiating from a central atom (see also BLOCK COPOLYMERS; COPOLYMERS, ALTERNATING; COPOLYMERIZATION; GRAFT COPOLYMERS).

Structure-based Nomenclature

For organic polymers that are regular, ie, have only one species of constitutional unit in a single sequential arrangement, and consist only of single strands, the IUPAC has promulgated a structure-based system of naming polymers (11). As originally devised by the Polymer Nomenclature Committee of the American Chemical Society (22), it consists of naming a polymer as poly(constitutional repeating unit), wherein the repeating unit is named as a bivalent organic radical according to the usual nomenclature rules for organic chemistry. It is important to note that in structure-based nomenclature the name of the constitutional repeating unit has no relationship to the source from which the unit was prepared. The name is simply that of the largest identifiable unit in the polymer, and locants for unsaturation, substituents, etc are dictated by the structure of the unit.

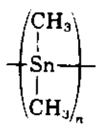
The steps involved in naming the constitutional repeating unit are (*1*) identification of the unit, taking into account the kinds of atoms in the main chain and the location of substituents; (*2*) orientation of the unit; and (*3*) naming of the unit. Examples of names for some common polymers are given in Table 3. Note that in this system parentheses are always used to enclose the repeating unit.

Structure-based nomenclature can be utilized to name polymers with great complexity, provided only that they be regular and single-stranded. Among these are polymers with constitutional repeating units which consist, themselves, of a series of smaller subunits; polymers with heteroatoms or heterocyclic ring systems in the main chain; and polymers with substituents on acyclic or cyclic subunits of constitutional repeating units. Structure-based nomenclature is also applicable to copolymers having a regular structure, regardless of the starting materials used, eg, poly(oxyethyleneoxyterephthaloyl). In principle, it should be possible to extend the existing structure-based nomenclature beyond regular, single-strand polymers to polymers that have reacted, cross-linked polymers, ladder polymers, and other more complicated systems.

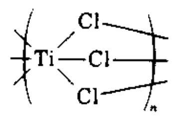
Structure-based nomenclature has gained acceptance in the scientific literature, eg, *Chemical Abstracts*, because it overcomes many of the deficiencies of source-based nomenclature.

Inorganic and Coordination Polymers. The nomenclature of regular single-strand inorganic and coordination polymers (qv) is governed by the same

ındamental principles as that for single-strand organic polymers (14). The name f such a polymer is that of the smallest structural repeating unit prefixed by ıe terms poly, *catena* (for linear chains) or other structural indicator, and des- ;nations for end groups. The structural units are named by the nomenclature ıles for inorganic and coordination chemistry. Some examples are



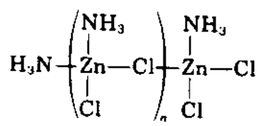
catena-poly[dimethyltin]



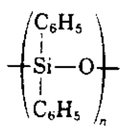
catena-poly[titanium-tri-μ-chloro]

$-\!(\mathrm{N{=}S})_n\!-$

catena-poly[nitrogen-μ-thio]



α-ammine-ω-(amminedichlorozinc)-*catena*-poly[(amminechlorozinc)-μ-chloro]



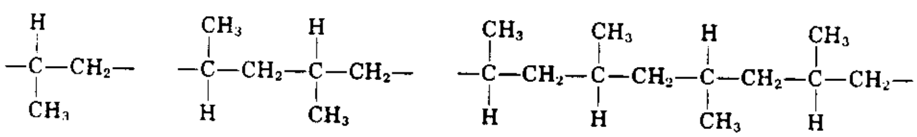
catena-poly[(diphenylsilicon)-μ-oxo]

$-\!(\mathrm{Ag{-}NC})_n\!-$

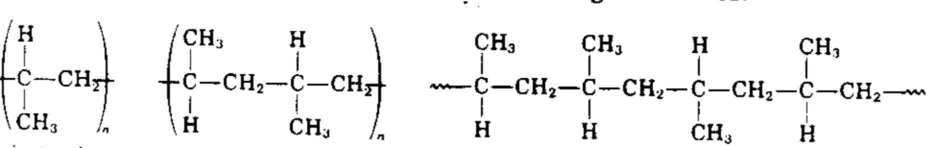
catena-poly[silver-μ-(cyano-*N*:*C*)]

Stereochemical Definitions and Notations. Structure-based nomenclature regular polymers (4) can denote stereochemical features if the repeating unit ed is the configurational unit, ie, a constitutional unit having one or more sites defined stereoisomerism (8). Structure-based names are then derived in the ual fashion. The various stereochemical features that are possible in a polymer ıst be defined.

Natta and co-workers introduced the concept of tacticity, ie, the orderliness the succession of configurational repeating units in the main chain of a polymer. r example, in poly(propylene), possible steric arrangements are shown in Fischer ɔjections displayed horizontally:



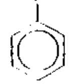
d the corresponding polymers have the following structures:

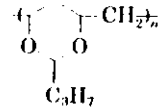
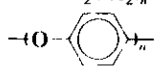
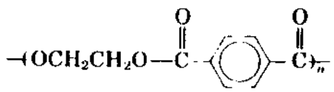
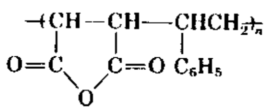


isotactic syndiotactic atactic

The isotactic polymer has only one species of configurational unit in a single uential arrangement and the syndiotactic polymer shows an alternation of figurational units that are enantiomeric, whereas in the atactic polymer the

Table 3. Examples of Systematic Structure-based Names for Polymers*

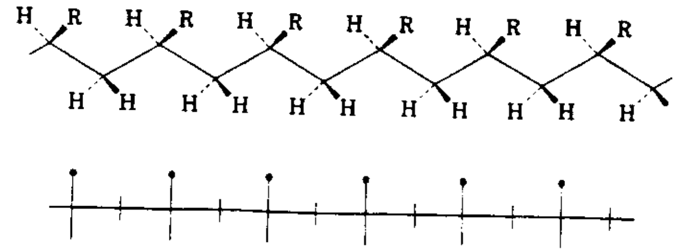
Structure	Structure-based name	Common (source-based) name
$-\!(CH_2CH_2)_n$	poly(methylene)	polyethylene
$-\!(CHCH_2)_n$ $\quad\vert$ $\quad CH_3$	poly(propylene)	polypropylene
$\quad CH_3$ $\quad\vert$ $-\!(C-CH_2)_n$ $\quad\vert$ $\quad CH_3$	poly(1,1-dimethylethylene)	polyisobutylene
$-\!(C{=}CHCH_2CH_2)_n$ $\quad\vert$ $\quad CH_3$	poly(1-methyl-1-butenylene)	polyisoprene
$-\!(CHCH_2)_n$ $\quad\vert$ 	poly(1-phenylethylene)	polystyrene
$-\!(CHCH_2)_n$ $\quad\vert$ $\quad Cl$	poly(1-chloroethylene)	poly(vinyl chloride)
$-\!(CHCH_2)_n$ $\quad\vert$ $\quad CN$	poly(1-cyanoethylene)	polyacrylonitrile
$-\!(CHCH_2)_n$ $\quad\vert$ $\quad OOCCH_3$	poly(1-acetoxyethylene)	poly(vinyl acetate)
$\quad F$ $\quad\vert$ $-\!(CCH_2)_n$ $\quad\vert$ $\quad F$	poly(1,1-difluoroethylene)	poly(vinylidene fluoride)

$-\!\!\left(CF_2CF_2\right)_n$	poly(difluoromethylene)	polytetrafluoroethylene
	poly[(2-propyl-1,3-dioxane-4,6-diyl)methylene]	poly(vinyl butyral)
$-\!\!\left(C(CH_3)(COOCH_3)-CH_2\right)_n$	poly[1-(methoxycarbonyl)-1-methylethylene]	poly(methyl methacrylate)
$-\!\!\left(OCH_2CH_2\right)_n$	poly(oxyethylene)	poly(ethylene oxide)
	poly(oxy-1,4-phenylene)	poly(phenylene oxide)
	poly(oxyethyleneoxyterephthaloyl)	poly(ethylene terephthalate)
$-\!\!\left(NH-C(=O)(CH_2)_4C(=O)-NH(CH_2)_6\right)_n$	poly(iminoadipoyliminohexamethylene)	poly(hexamethylenediamine-*co*-adipic acid) or poly(hexamethylene adipamide)
	poly[2,5-dioxotetrahydrofuran-3,4-diyl(phenylethylene)]	poly(maleic anhydride-*co*-styrene)

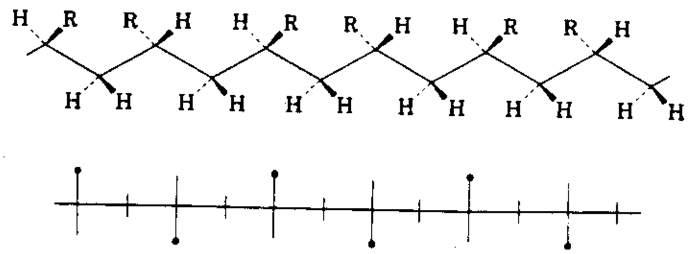
[a] Ref. 6. Courtesy of *Pure and Applied Chemistry*.

molecules have equal numbers of the possible configurational units in a random sequence distribution. This can be generalized as follows:

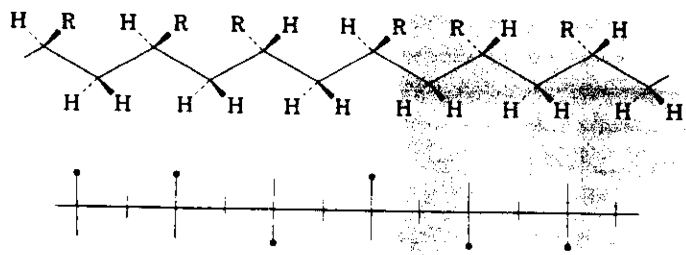
Isotactic:



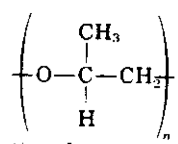
Syndiotactic:



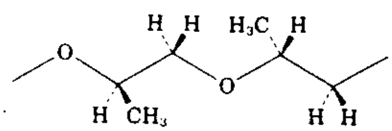
Atactic:

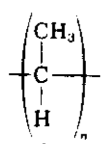


Further examples of tactic polymers are

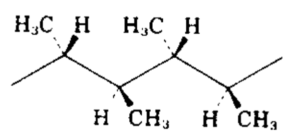


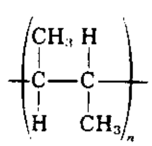
isotactic poly(oxypropylene)



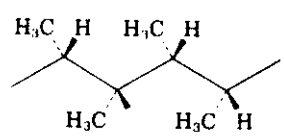


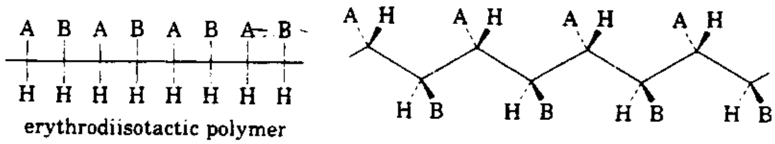
isotactic poly(ethylidene)



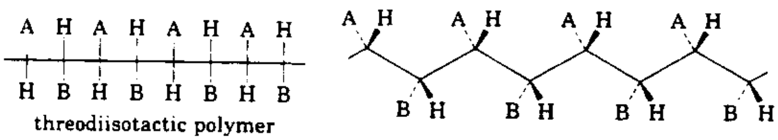


syndiotactic poly(ethylidene)

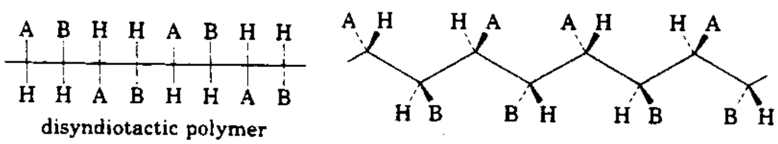




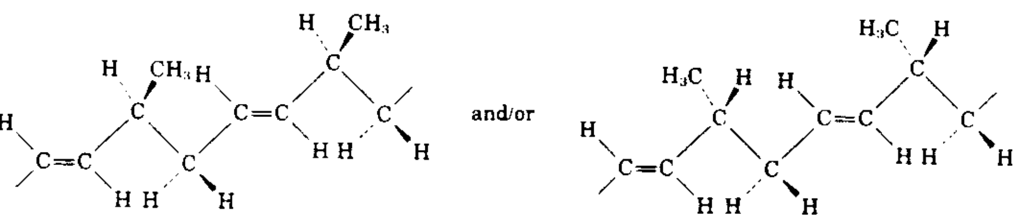
erythrodiisotactic polymer



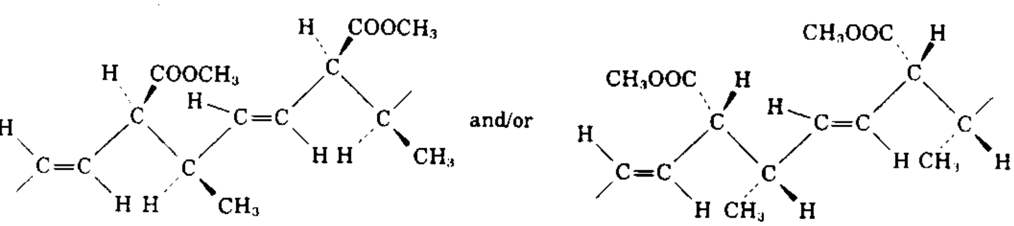
threodiisotactic polymer



disyndiotactic polymer

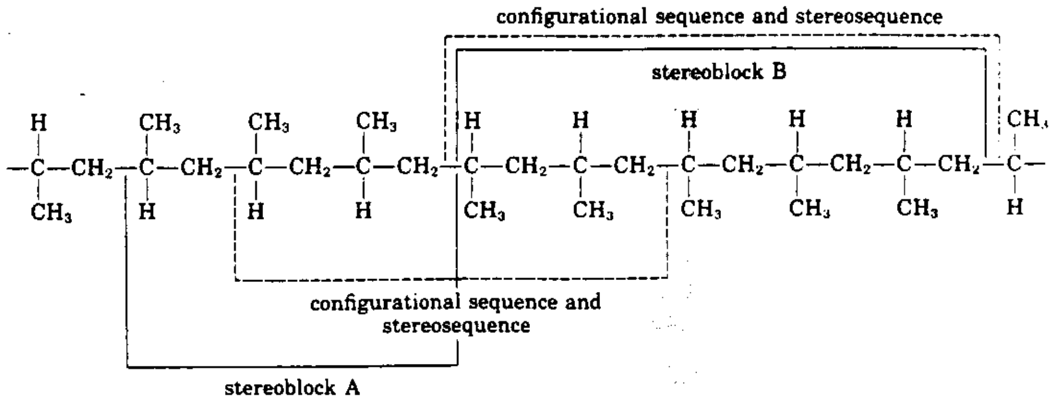


isotactic poly(3-methyl-*trans*-1-butenylene) or transisotactic poly(3-methyl-1-butenylene)



diisotactic poly[*threo*-3(methoxycarbonyl)-4-methyl-*trans*-1-butenylene] or transthreodiisotactic poly[3-(methoxycarbonyl)-4-methyl-1-butenylene]

The concept of a stereoblock is illustrated in the following example of a regular poly(propylene) chain, in which the stereoblocks are denoted by ⌐¬. The sequence of identical relative configurations of adjacent units that characterizes a stereoblock is terminated at each end of the block. The dashed line ┌┄┐ encloses a configurational sequence, which may or may not be identical with a stereoblock.



The published IUPAC document (4) should be consulted for more complex cases and for the notations used to designate conformations of polymer molecules (bond lengths, bond angles, torsion angles, helix sense, isomorphous and enantiomorphous structures, line repetition groups and symmetry elements, etc) as well as for the various stereochemical definitions (see also MICROSTRUCTURE; STEREOREGULAR POLYMERS).

Trade Names and Abbreviations

Because the systematic names of polymers can be cumbersome, trade names and abbreviations are frequently used as a shortcut in industrial literature and

Table 4. List of Abbreviations from the 1986 IUPAC Recommendations[a]

PAN	polyacrylonitrile
PCTFE	polychlorotrifluoroethylene
PEO	poly(ethylene oxide)
PETP[b]	poly(ethylene terephthalate)
PE	polyethylene
PIB	polyisobutylene
PMMA	poly(methyl methacrylate)
POM	poly(oxymethylene); polyformaldehyde
PP	polypropylene
PS	polystyrene
PTFE	polytetrafluoroethylene
PVAC	poly(vinyl acetate)
PVAL	poly(vinyl alcohol)
PVC	poly(vinyl chloride)
PVDC	poly(vinylidene dichloride)
PVDF	poly(vinylidene difluoride)
PVF	poly(vinyl fluoride)

[a] Ref. 9.
[b] The abbreviation PET is commonly used in the literature.

oral communication. For example, the simpler generic name nylon-6,6 for a polyamide, where the first number refers to the number of carbon atoms of the diamine and the second number to that of the diacid fragment, appears often in the literature rather than the systematic name poly(iminoadipoyliminohexamethylene). Useful compilations of trade names for polymers can be found in Refs. 23 and 24.

Perhaps the most widely used shortcut is the use of abbreviations for common industrial polymeric materials. The IUPAC recognizes that there may be advantages in some cases to use abbreviations, but urges that each abbreviation be fully defined the first time it appears in the text and that no abbreviation be used in titles of publications. Because there are inherent difficulties in assigning systematic and unique abbreviations to polymeric structures, only a short list has the IUPAC's official sanction (9,10) (Table 4). ISO has published a more extensive list (25), and the American Chemical Society has compiled a master list of all known abbreviations in the polymer field (26).

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NORBERT M. BIKALES
National Science Foundation
Secretary (1978–1987), IUPAC Commission on Macromolecular Nomenclature

NONAQUEOUS DISPERSIONS. See COATINGS.

NONCOMBUSTIBLE FABRICS. See FLAMMABILITY.

NONDESTRUCTIVE TESTING. See TEST METHODS.

NON-NEWTONIAN FLOW. See VISCOELASTICITY.

NONWOVEN FABRICS

SURVEY

Nonwoven fabrics are porous, textilelike materials, usually in flat she form, composed primarily or entirely of fibers assembled in webs (1–3). The fabrics, also called bonded fabrics, formed fabrics, or engineered fabrics, are ma ufactured by processes other than spinning, weaving, or knitting. The thickn of the sheets may vary from 25 μm to several centimeters, and the weight fr 10 g/m^2 to 1 kg/m^2. A sheet may resemble paper or a woven or knitted fabric appearance and may have a unique texture or pattern. It may be as compact a crisp as paper or supple and drapable as a conventional textile; it may be resili or limp. Its tensile properties may be barely self-sustaining or so high that i impossible to tear, abrade, or damage the sheet by hand. The fiber compone one or several types, may be natural or synthetic, from 1–3-mm long to endl The tensile properties may depend on frictional forces or a film-forming polym additive functioning as an adhesive binder. All or some of the fibers may welded by heat or solvent. A scrim, gauze, netting, yarn, or other conventi sheet material may be added to one or both faces, or embedded within as r forcement. The nonwoven fabric may be incorporated as a component in a c posite structure.

Felted fabrics from animal hairs, eg, wool (qv), are not included even th

an·hy·drous \(ˈ)anˈhīdrəs\ *adj* [modif. (influenced by *hydr-*, *hydro-*) of Gk *anydros* waterless, fr. *an-* + *-ydros* (fr. *hydōr* water) — more at WATER] : destitute of water — used of water of crystallization, dissolved or combined water, adsorbed water

HERMES DECLARATION
EXHIBIT 11

Pure Appl. Chem., Vol. 73, No. 9, pp. 1511–1519, 2001.

INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY

MACROMOLECULAR DIVISION
COMMISSION ON MACROMOLECULAR NOMENCLATURE*

GENERIC SOURCE-BASED NOMENCLATURE FOR POLYMERS

(IUPAC Recommendations 2001)

Prepared by a Working Group consisting of

R. E. BAREISS (Germany), R. B. FOX (USA), K. HATADA (Japan), K. HORIE (UK), A. D. JENKINS (UK), J. KAHOVEC (Czech Republic), P. KUBISA (Poland), E. MARÉCHAL (France), I. MEISEL (Germany), W. V. METANOMSKI (USA), I. MITA (Japan), R. F. T. STEPTO (UK), AND E. S. WILKS (USA)

Prepared for publication by
E. MARÉCHAL[1] AND E. S. WILKS[2,†]

[1]*Université Pierre et Marie Curie (Paris VI), Laboratoire de Synthèse Macromoléculaire, Boîte 184, 4 Place Jussieu F-75252, Paris Cédex 05, France;* [2]*113 Meriden Drive, Canterbury Hills, Hockessin, DE 19707 USA*

*Membership of the Commission during the preparation of this report (1993–1999) was as follows:
***Titular Members*:** R. E. Bareiss (Germany, 1983–1993); M. Barón (Argentina, from 1996, Secretary from 1998); K. Hatada (Japan, 1989–1997); M. Hess (Germany, from 1998); K. Horie (Japan, from 1997); J. Kahovec (Czech Republic, to 1999); P. Kubisa (Poland, from 1999); E. Maréchal (France, from 1994); I. Meisel (Germany, from 2000); W. V. Metanomski (USA, 1994–1999); C. Noël (France, to 1997); V. P. Shibaev (Russia, to 1995); R. F. T. Stepto (UK, 1989–1999, Chairman to 1999); E. S. Wilks (USA, from 2000); W. J. Work (USA, 1987–1999, Secretary, 1987–1997); ***Associate Members*:** M. Barón (Argentina,1991–1995); K. Hatada (Japan, 1998–1999); J.-I. Jin (Korea, from 1993); M. Hess (Germany, 1996–1997); K. Horie (Japan, 1996–1997); O. Kramer (Denmark, from 1996); P. Kubisa (Poland, 1996–1998); E. Maréchal (France, 1991–1993); I. Meisel (Germany, 1997–1999); S. Penczek (Poland, from 1994); L. Shi (China, 1987–1995); V. P. Shibaev (Russia, 1996–1999); E. S. Wilks (USA, 1998–1999).

†Corresponding author

Generic source-based nomenclature for polymers

(IUPAC Recommendations 2001)

Abstract: The commission has already published two documents on the source-based names of linear copolymers and nonlinear polymers; however, in some cases this nomenclature leads to ambiguous names. The present document proposes a generic source-based nomenclature that solves these problems and yields clearer source-based names. A generic source-based name comprises two parts:

1) polymer class (generic) name followed by a colon
2) the actual or hypothetical monomer name(s), always parenthesized in the case of a copolymer

The formula, the structure-based name, the source-based name, and the generic source-based name of the polymer are given for each example in the document. In some cases, only generic source-based give unambiguous names, for example, when a polymer has more than one name or when it is obtained through a series of intermediate structures. The rules concern mostly polymers with one or more types of functional group or heterocyclic system in the main chain, but to some extent they are also applicable to polymers with side-groups, carbon-chain polymers such as vinyl or diene polymers, spiro and cyclic polymers, and networks.

CONTENTS

1. INTRODUCTION

The IUPAC Commission on Macromolecular Nomenclature has published three documents [1–3] on the structure-based nomenclature for polymers that enable most polymers, except networks, to be named. The Commission has also produced two documents [4,5] on the source-based nomenclature of linear copolymers and nonlinear polymers. In general, source-based names are simpler and less rigorous than structure-based names. However, there are cases in which the simplicity of the source-based nomenclature leads to ambiguous names for polymers. For example, the condensation of a dianhydride (A) with a diamine (B) gives first a polyamide-acid, which can be cyclized to a polyimide; however, both products have the same name poly(A-*alt*-B) according to current source-based nomenclature. If the class name of the polymer "amide-acid" or "imide" is incorporated in the name, differentiation is easily accomplished. Even in cases where only a single product is formed, use of the class name (generic name) may help to clarify the structure of the polymer, especially if it is very complex.

Examples of ambiguous names exist also for homopolymers. The source-based name "polybutadiene" does not indicate whether the structure is 1,2-, 1,4-*cis*-, or 1,4-*trans*-; supplementary information is needed to distinguish between the possibilities.

It is the objective of the present document to introduce a generic nomenclature system to solve these problems, and to yield better source-based names.

Most trivial names, such as polystyrene, are source-based names. Hitherto, the Commission has not systematically recommended source-based names for homopolymers because it considered that the more rigorous structure-based names were more appropriate for scientific communications. However, since the publication of "Nomenclature of Regular Single-Strand Organic Polymers" in 1976, scientists, in both industry and academia, have continued to use trivial names. Even the Commission itself adopted (1985) a source-based nomenclature for copolymers owing to its simplicity and practicality. Based on these facts, the Commission has now decided to recommend source-based nomenclature as an alternative official nomenclature for homopolymers. In this document, the rules for generating source-based names for homopolymers are described. Consequently, source-based and structure-based names are available for most polymers.

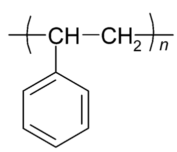
Names of the monomers in the source-based names of polymers should preferably be systematic but they may be trivial if well established by usage. Names of the organic groups, as parts of constitutional repeating units (CRU) in structure-based names, are those based on the principles of organic nomenclature and recommended by the 1993 *A Guide to IUPAC Nomenclature of Organic Compounds* [6].

2. SOURCE-BASED NOMENCLATURE FOR HOMOPOLYMERS

RULE 1

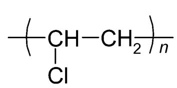
The source-based name of a homopolymer is made by combining the prefix "poly" with the name of the monomer. When the latter consists of more than one word, or any ambiguity is anticipated, the name of the monomer is parenthesized.

Example 1.1



Source-based name:
polystyrene
Structure-based name:
poly(1-phenylethylene)

Example 1.2



Source-based name:
poly(vinyl chloride)
Structure-based name:
poly(1-chloroethylene)

3. GENERIC NOMENCLATURE

3.1 Fundamental principles

The basic concept for generic source-based nomenclature is very simple; just add the polymer class name to the source-based name of the polymer. Addition of the polymer class name is frequently

OPTIONAL; in some cases, the addition is necessary to avoid ambiguity or to clarify. However, the addition is undesirable if it fails to add clarification.

The system presented here can be applied to almost all homopolymers, copolymers, and others, such as networks. However, generic source-based nomenclature should not be considered as a third nomenclature system to be added to the other two systems of nomenclature; it must be considered as an auxiliary system and a simple extension of current source-based nomenclature. When the generic part of the name is eliminated from the name of a polymer, the well-established source-based name remains.

3.2 General rules

RULE 2

A generic source-based name of a polymer has two components in the following sequence: (1) a polymer class (generic) name (polyG) followed by a colon and (2) the actual or hypothetical monomer name(s) (A, B, etc.), always parenthesized in the case of a copolymer. In the case of a homopolymer, parentheses are introduced when it is necessary to improve clarity.

polyG:A polyG:(B) polyG:(A-*co*-B) polyG:(A-*alt*-B)

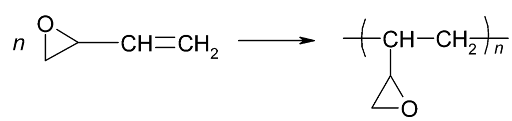
Note 1 The polymer class name (generic name) describes the most appropriate type of functional group or heterocyclic ring system.

Note 2 All the rules given in the two prior documents on source-based nomenclature [4,5] can be applied to the present nomenclature system, with the addition of the generic part of the name.

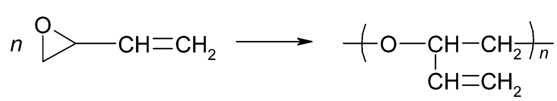
Note 3 A polymer may have more than one name; this usually occurs when it can be prepared in more than one way.

Note 4 If a monomer or a pair of complementary monomers can give rise to more than one polymer, or if the polymer is obtained through a series of intermediate structures, the use of generic nomenclature is essential (see examples 2.1, 2.3, and 2.4).

Example 2.1



I



II

Generic source-based name:

I. polyalkylene:vinyloxirane

II. polyether:vinyloxirane

Source-based names:

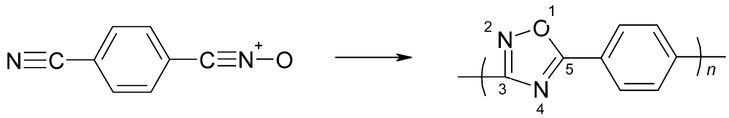
I and II have the same source-based name: poly(vinyloxirane).

Structure-based names:

I. poly(1-oxiranylethylene)

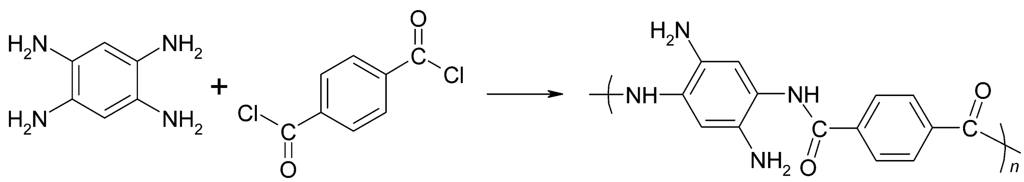
II. poly[(oxy(1-vinylethylene)]

Example 2.2

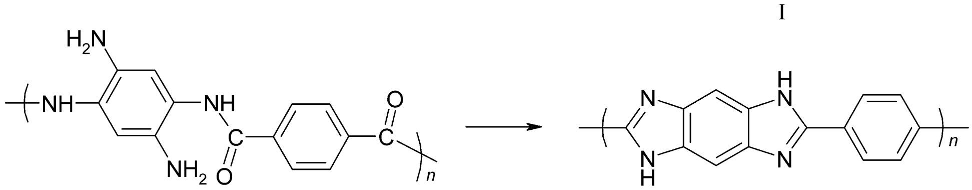


Generic source-based name:
    polyoxadiazole:(4-cyanobenzonitrile *N*-oxide)
Structure-based name:
    poly(1,2,4-oxadiazole-3,5-diyl-1,4-phenylene)

Example 2.3



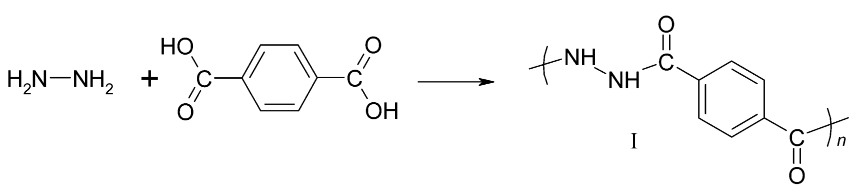
I



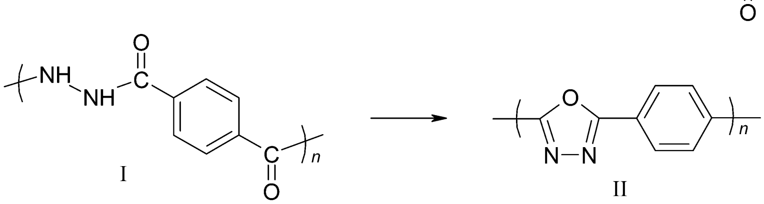
I II

Generic source-based name:
    I. polyamide:[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]
    II. polybenzimidazole:[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]
Source-based name:
    I and II have the same source-based name:
    poly[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]
Structure-based names:
    I. poly[imino (2,5-diamino-1,4-phenylene)iminoterephthaloyl]
    II. poly[(1,5-dihydrobenzo[1,2-*d*:4,5-*d*′]diimidazole-2,6-diyl)-1,4-phenylene]

Example 2.4



I



I II

Generic source-based names:
    I. polyhydrazide:[hydrazine-*alt*-(terephthalic acid)]
    II. polyoxadiazole:[hydrazine-*alt*-(terephthalic acid)]

Source-based name:

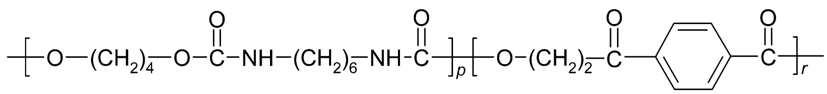
I and II have the same source-based name: poly[hydrazine-*alt*-(terephthalic acid)]

Structure-based names:

I. poly(hydrazine-1,2-diylterephthaloyl)

II. poly(1,3,4-oxadiazole-2,5-diyl-1,4-phenylene)

Example 2.5



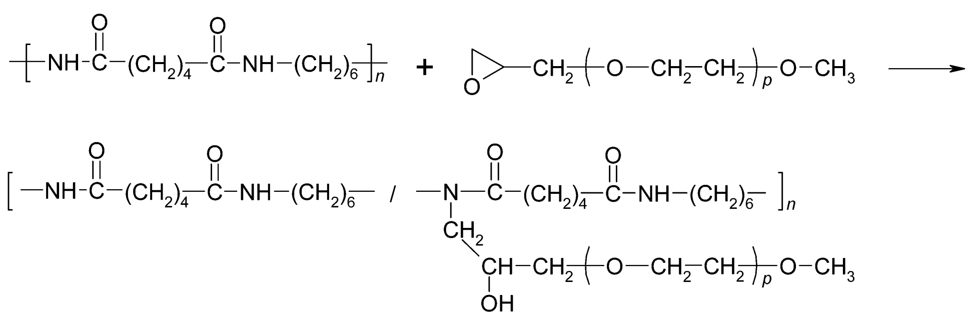
Generic source-based names:

polyurethane:[butane-1,4-diol-*alt*-(hexane-1,6-diyl diisocyanate)]-*block*-polyester: [(ethylene glycol)-*alt*-(terephthalic acid)]

Structure-based name:

poly(oxybutane-1,4-diyloxycarbonyliminohexane-1,6-diyliminocarbonyl)-*block*-poly(oxyethyleneoxyterephthaloyl)

Example 2.6



Generic source-based name:

polyamide:[hexane-1,6-diamine-*alt*-(adipic acid)]-*graft*-polyether:(ethylene oxide)

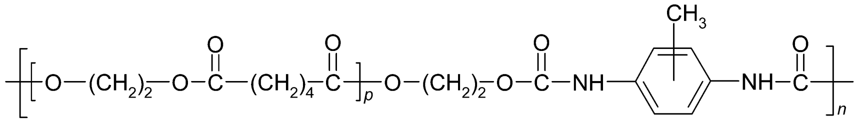
Note 5 It is assumed that this reaction is limited to only one graft for each CRU.

RULE 3

When more than one type of functional group or heterocyclic system is present in the polymer structure, names should be alphabetized; for example, poly(GG′):(A-*alt*-B).

Note 6 It is preferable, but not mandatory, to cite all generic classes.

Example 3.1



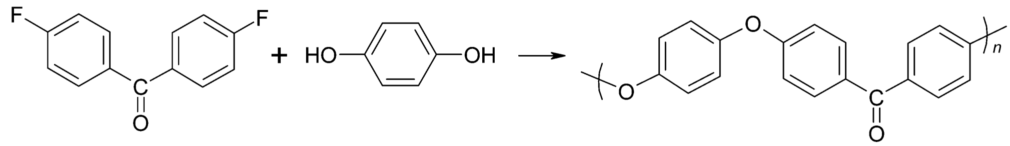
Generic source-based name:

polyesterurethane:{α,ω-dihydroxyoligo[(ethylene glycol)-*alt*-(adipic acid)]-*alt*-(2,5-tolylene diisocyanate)}

Structure-based name:

poly{[oligo(oxyethyleneoxyadipoyl)]oxyethyleneoxycarbonylimino(x-methyl-1,4-phenylene)iminocarbonyl)}

Example 3.2



Generic source-based name:

polyetherketone:(4,4′-difluorobenzophenone-*alt*-hydroquinone)

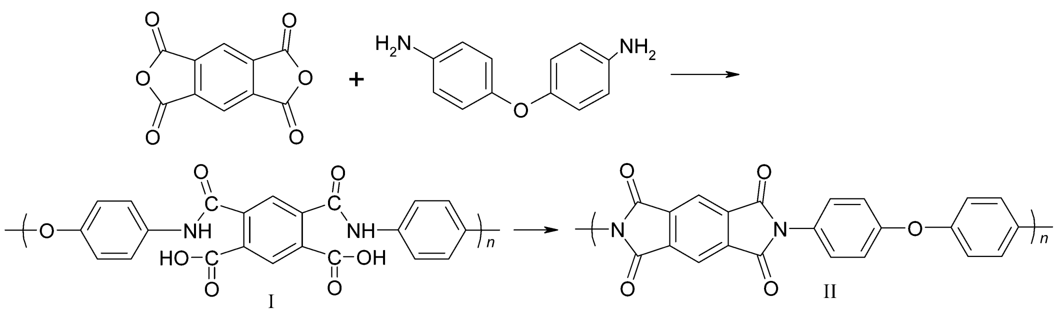
Structure-based name:

poly(oxy-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylene)

RULE 4

Polymer class names relevant only to the main chain are specified in the name; names of side-chain functional groups may also be included after a hyphen if they are formed during the polymerization reaction.

Example 4.1



Generic source-based names:

I. poly(amide-acid):[(pyromellitic dianhydride)-*alt*-(4,4′-oxydianiline)]
(Both carboxy groups result from the polymerization reaction.)

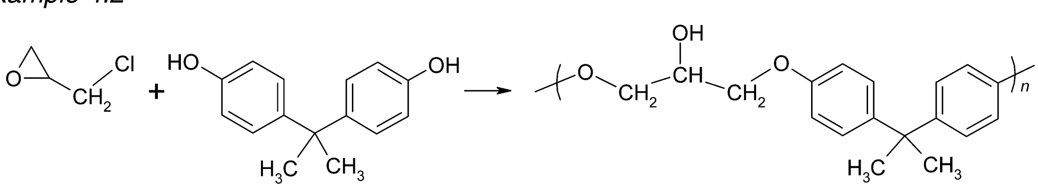
II. polyimide:[(pyromellitic dianhydride)-*alt*-(4,4′-oxydianiline)]

Structure-based names:

I. poly[oxy-1,4-phenyleneiminocarbonyl(4,6-dicarboxy-1,3-phenylene)carbonylimino-1,4-phenylene]

II. poly[(5,7-dihydro-1,3,5,7-tetraoxobenzo[1,2-*c*:4,5-*c*′]dipyrrole-2,6(1*H*,3*H*)-diyl)-1,4-phenyleneoxy-1,4-phenylene]

Example 4.2



Generic source-based names:

poly(ether-alcohol):(epichlorohydrin-*alt*-bisphenol A)

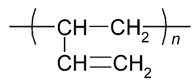
Structure-based name:

poly[oxy(2-hydroxypropane-1,3-diyl)oxy-1,4-phenylene(1-methylethane-1,1-diyl)-1,4-phenylene]

RULE 5

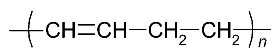
In the case of carbon-chain polymers such as vinyl polymers or diene polymers, the generic name is to be used only when different polymer structures may arise from a given monomeric system.

Example 5.1



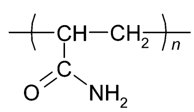
Generic source-based name:
    polyalkylene:(buta-1,3-diene)
Source-based name:
    poly(buta-1,3-diene)
Structure-based name:
    poly(1-vinylethylene)

Example 5.2



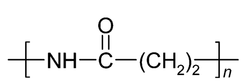
Generic source-based name:
    polyalkenylene:buta-1,3-diene
Source-based name:
    poly(buta-1,3-diene)
Structure-based name:
    poly(but-1-ene-1,4-diyl)

Example 5.3



Generic source-based name:
    polyalkylene:acrylamide
Structure-based name:
    poly[1-(aminocarbonyl)ethylene]

Example 5.4



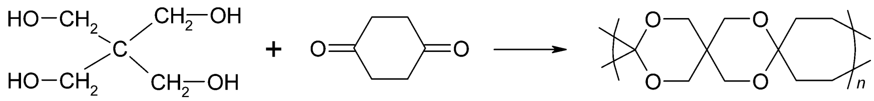
Generic source-based name:
    polyamide:acrylamide
Structure-based name:
    poly[imino(1-oxopropane-1,3-diyl)]

Note 7 The terms polyalkylene and polyalkenylene have been defined in ref. 7, p. 149.

4. FURTHER APPLICATIONS OF GENERIC NAMES

Generic source-based nomenclature can be extended to more complicated polymers such as spiro and cyclic polymers and networks.

Example 6.1



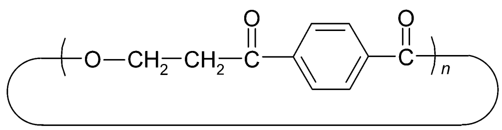
Generic source-based name:

polyspiroketal:{[2,2-bis(hydroxymethyl)-propane-1,3-diol]-*alt*-cyclohexane-1,4-dione}
or polyspiroketal:(pentaerythritol-*alt*-cyclohexane-1,4-dione)

Structure-based name:

poly[2,4,8,10-tetraoxaspiro[5.5]undecane-3,3,9,9-tetrayl-9,9-bis(ethylene)]

Example 6.2

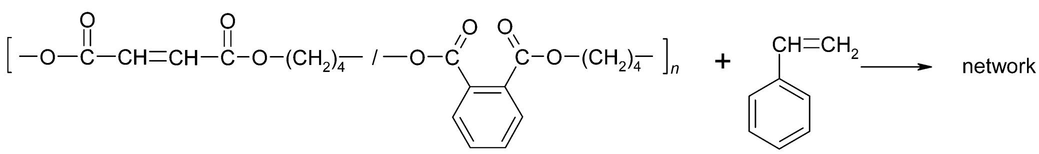


Generic source-based name:

cyclo-polyester:[(ethylene glycol)-*alt*-(terephthalic acid)]

Note 8 There is no IUPAC nomenclature for cyclic polymers.

Example 6.3



Generic source-based name:

polyester:{butane-1,4-diol-*alt*-[(maleic anhydride);(phthalic anhydride)]}-*net*-polyalkylene:(maleic anhydride)-*co*-styrene]

5. REFERENCES

1. "Nomenclature of regular single-strand organic polymers, 1975", *Pure Appl. Chem.* **48**, 373–385 (1976). Reprinted as chapter 5 in Ref. 7.
2. "Nomenclature of regular double-strand (ladder and spiro) organic polymers 1993", *Pure Appl. Chem*. **65**, 1561–1580 (1993).
3. "Structure-based nomenclature for irregular single-strand organic polymers 1994", *Pure Appl. Chem*. **66**, 873–889 (1994).
4. "Source-Based Nomenclature for Copolymers 1985", *Pure Appl. Chem.* **57**, 1427–1440 (1985). Reprinted as chapter 7 in Ref. 7.
5. "Source-based nomenclature for non-linear macromolecules and macromolecular assemblies", *Pure Appl. Chem.* **69**, 2511–2521 (1997).
6. *A Guide to IUPAC Nomenclature of Organic Compoun*ds, R. Panico, W. H. Powell, J-C. Richer (Eds.), Blackwell Scientific Publications, Oxford (1993).
7. *Compendium of Macromolecular Nomenclature*, W. V. Metanomski (Ed.), Blackwell Scientific Publications, Oxford (1991).

HERMES DECLARATION
EXHIBIT 12

SALES BULLETIN

DATE **01/05/05** SUBJECT **High Strength Sutures** NUMBER **UE133**

A Biomechanical Analysis of High Strength Sutures

Recently, Stephen S. Burkhart, M.D., conducted a biomechanical analysis of new high strength sutures used primarily for arthroscopic shoulder surgery. The purpose of the study was to determine the type of braided suture that produces the optimal knot configuration maximizing both knot and loop security. The high strength sutures tested were #2 FiberWire®, #2 OrthoCord™, Herculine™, MaxBraid, UltraBraid™, and Ethibond™ (2 mm FiberTape™ was also included in this study).

Conclusions

- Tying a surgeon's knot with #2 FiberWire significantly increases knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- Tying a surgeon's knot or sliding knot with #2 FiberWire provides the optimum balance of loop and knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire provides the greatest loop security when tying a Weston or Roeder knot compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire has the greatest knot security when tying a surgeon's knot compared to #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond. Although #2 OrthoCord had the smallest loop circumference when tying a surgeon's knot the difference between the loop circumference of #2 FiberWire and #2 OrthoCord **was not** statistically significant.
- In straight pull-testing, #2 FiberWire had the highest ultimate strength compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire had the smallest percentage of elongation compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.

Methods & Materials

Six #2 sutures were tested, FiberWire (polyethylene & polyester), Ethibond (polyester), OrthoCord (polydioxnone & polyester), Herculine (polyethylene), MaxBraid (polyethylene), and UltraBraid (polyethylene with & without a monofilament polypropylene marker). Three knots were used, the Roeder & Weston knots with three reversing half-hitches on alternating posts as well as a static surgeon's knot. Additionally, 2 mm FiberTape (polyethylene & polyester) were tied using four alternating throws. All total 133 knots were tied.

All knots were tied around a 30 mm circumference post to assure consistent loop circumference by Stephen S. Burkhart, M.D., a senior arthroscopic surgeon (Figure 1). Before testing, the knot stack was measured using calipers (Figure 2).

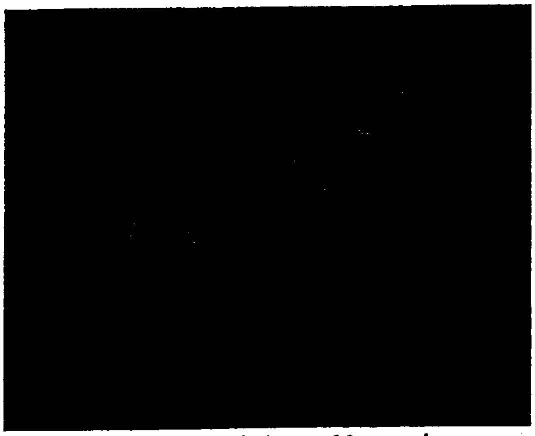


Figure 1: Knot tied over 30 mm pin.

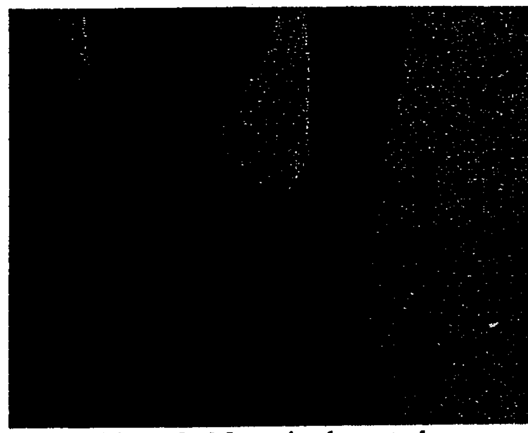


Figure 2: Measuring knot stack.

Each loop was mounted on an Instron materials testing system (model 5544, Instron, Canton, MA) to test knot and loop security. Fixtures were mounted to the base and crosshead of the Instron with two 3.95 mm diameter rods held parallel. Each loop was placed around the rods with the knots centered between the two rods (Figure 3). A 5N preload was applied at 1 mm/s and then pulled to failure at 1 mm/s. Data was collected at 500 Hz.

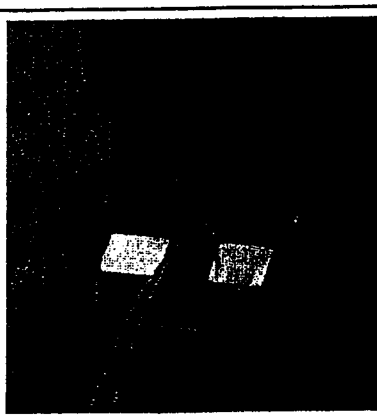


Figure 3: Instron test set up.

The loop circumference was measured at the 5N preload to assess each knot's ability to maintain a tight loop without slippage (loop security). The loop circumference was calculated based on equation 1 where C_l = loop circumference, d = rod diameter, and x = crosshead displacement measured for the center of each rod.

Equation 1: $C_l = \pi d \times 2(x)$

Knot security was measured as the maximum force to failure at 3 mm of crosshead displacement or suture breakage during single pull load testing (force to failure and failure mode were recorded). Three millimeters of elongation was selected as the failure mode because 3 mm or more is generally accepted in the literature. For statistical analysis one way analyses of variance (ANOVA) were used. *Post hoc* pairwise multiple comparisons were made using a Biferroni t-test. A significance level of 0.05 was used for all analyses.

HERMES DECLARATION
EXHIBIT 13

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310

Test Report: # TEST021104

Part number: DT PS05 T2	Rev: N/A	Description: #2 Fiberwire MED2174 Coated and Uncoated USIPG Dyed	Material: Polyethylene, Polyester
Vendor Name: Pearsalls Brian Hallett.		Lot Numbers: N/A	Number Tested: 3/2
Performed by: Ashley Holloway		Type of Test: Knot Tiedown	Date: 02/16/04

Test Objective:

To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture.

Materials and Methods:

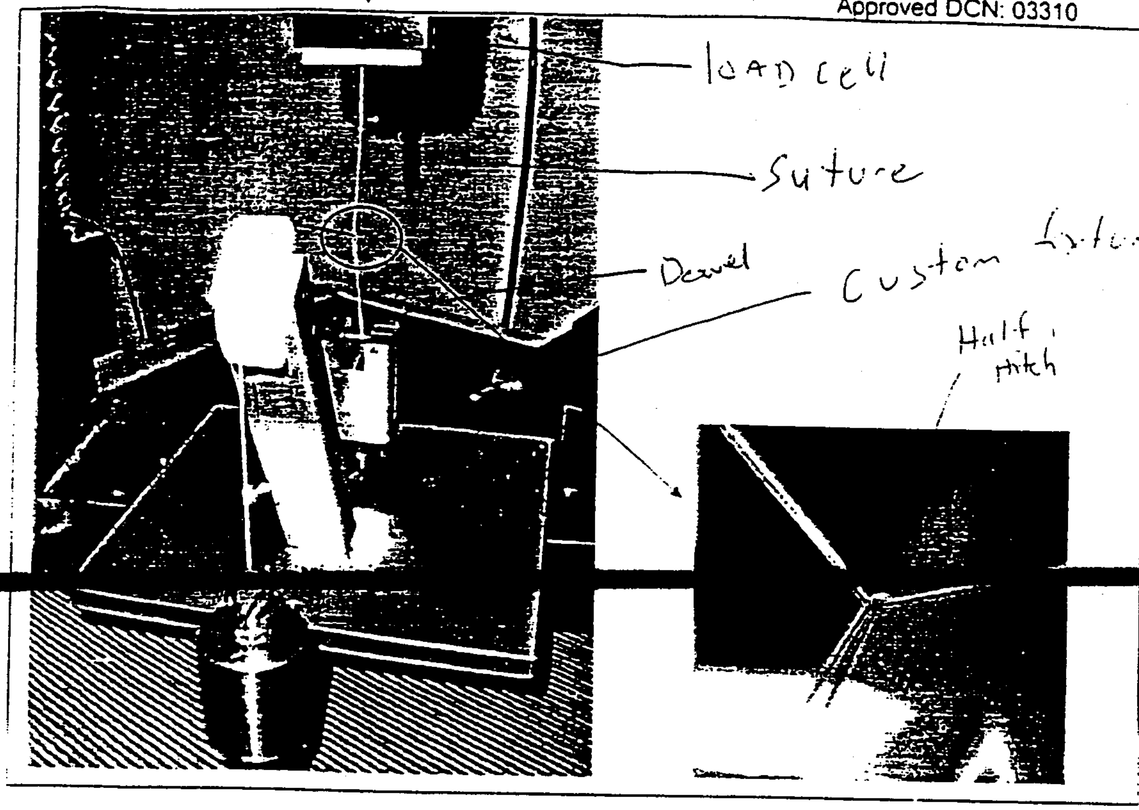
The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture consistently. The loop was then loaded at 12 in/min for 30mm and data was collected at 200 Hz. The peak load required to cause the half hitch to slip was recorded and used for data analysis purposes.

DEPUY MITEK
EXHIBIT 343
04cv12457

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310

↑ load cell movement



Data Analysis/Conclusions:

A mean peak force of 12.7 N was recorded for the coated suture. This force represents the force required to initiate slippage of the half hitch. A mean peak force of 32.9 N was recorded for the uncoated suture. A significantly greater amount of force was required to advance the uncoated suture.

2/16/04

Sample ID: coated_uncoated suture_1_021004.mss
Method: Suture Test.msm

Test Date: 2/11/04
Operator: Ashley Holloway

Sample Information:

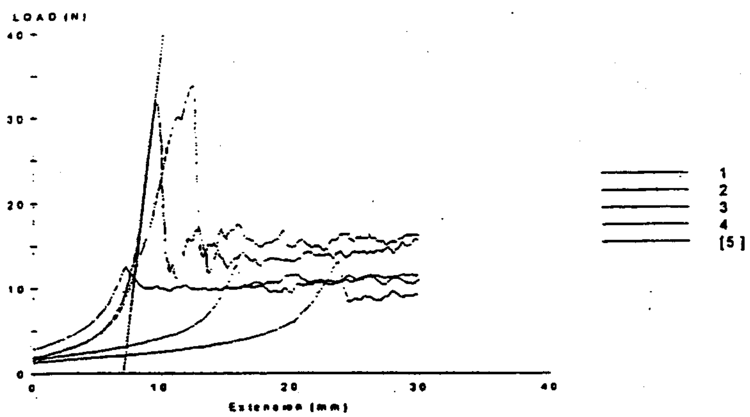
Name	Value
Lot Number	n/a
Part Number	Coated/Uncoated suture test
Revision Level	#2 Fiberwire

Specimen Results:

Specimen #	Peak Load Coated (N)		Specimen #	Peak Load Noncoated (N)
1	12.43		4	34.04
2	13.08		5	31.71
3	12.64			
Mean	12.72			32.88
Std. Dev.	0.33			1.65
Minimum	12.43			31.71
Maximum	13.08			34.04

Calculation Inputs:
Test Inputs:

Name	Value	Units
Break Threshold	5.620	lbf
Brk Sensitivity	95	%
Data Acq. Rate	200.0	Hz
Ext Limit HI	30.0	mm
Initial Speed	300.00	mm/min
Load Limit HI	150	N
MaxSpecimens	999	
Outer Loop Rate	100	Hz
Slack Pre-Load	5.00	N
Slowdown Extension	0.000	in
Slowdown Load	0.000	lbf
Slowdown Strain	0.000	%
Test Speed	305.00	mm/min



HERMES DECLARATION
EXHIBIT 14

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(71) Applicant
Fly Fishing Technology Limited

(Incorporated in the United Kingdom)

Units 3/4, Ffrwdgrech Industrial Estate, Brecon, Powys, LD3 8LA, United Kingdom

(72) Inventor
Paul David Burgess

(74) Agent and/or Address for Service
Wynne-Jones Lainé & James
Morgan Arcade Chambers, 33 St. Mary Street, Cardiff, Glamorgan, CF1 2AB, United Kingdom

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester and/or nylon, and the braid may be coated with a sheath of polyurethane.

GB 2 218 312 A

2218312

"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

CLAIMS

1. A fishing line of braided construction, some braid filaments being of high tenasile polythene thread and other filaments being of poilyester and/or nylon.

2. A line as claimed in Claim 1,, wherein the other filaments include polyester maulti-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monorfilaments.

4. A line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polyyurethane.

5. A line as claimed in any preeceding Claim, wherein the polythene is that sold undeer the Trade Mark DYNEEMA.

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HERMES DECLARATION
EXHIBIT 15 – PART 1 OF 8

1W 1270368

THE UNITED STATES OF AMERICA

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UNITED STATES DEPARTMENT OF COMMERCE
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February 04, 2005

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APPLICATION NUMBER: *07/838,511*
FILING DATE: *February 19, 1992*
PATENT NUMBER: *5,314,446*
ISSUE DATE: *May 24, 1994*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

N. Woodson

N. WOODSON
Certifying Officer

PART (1) OF (4) PART(S)

A.K. 838511

20X

07 838511

PATENT DATE MAY 24 1994

PATENT NUMBER 5314446

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT
07/838,511	02/19/92	606		1504

ALASTAIR W. HUNTER, BRIDGEWATER, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ;
MARK STECKEL, MAINEVILLE, OH.

CONTINUING DATA*******************
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FOREIGN/PCT APPLICATIONS**********
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FOREIGN FILING LICENSE GRANTED 03/05/92

Foreign priority claimed / 35 USC 119 conditions met / Verified and Acknowledged (Examiner's Initials)	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
☐ yes ☐ no / ☐ yes ☐ no / GM		NJ	3	24	1	$770.00	ETH-782

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

STERILIZED HETEROGENEOUS BRAIDS

U.S. DEPT. of COMM.-Pat. & TM Office—PTO-436L (rev. 10-78)

PARTS OF APPLICATION FILED SEPARATELY

NOTICE OF ALLOWANCE MAILED	PREPARED FOR ISSUE 12/29/93		CLAIMS ALLOWED	
11-18-93	CHRIS RAYMOND, Assistant Examiner	E. Simms, Docket Clerk	Total Claims 12	Print Claim 1

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Sheets Drwg.	Figs. Drwg.
3	3

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U.S. PATENT APPLICATION

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT
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APPLICANT

ALASTAIR W. HUNTER, BRIDGEWATER, NJ; DENNIS D. JAMIOLKOWSKI, LONG VALLEY, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ; MARK STECKEL, MAINEVILLE, OH.

CONTINUING DATA*******************
VERIFIED

FOREIGN/PCT APPLICATIONS**********
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STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.
NJ	3	24	1	$ 770.00	ETH-782

ADDRESS

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

TITLE

STERILIZED HETEROGENEOUS BRAIDS

This is to certify that annexed hereto is a true copy from the records of the United States Patent and Trademark Office of the application as filed which is identified above.

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Date Certifying Officer

07 838511

PATENT APPLICATION SERIAL NO.______________

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

DF11186 02/28/92 07838511 10-0750 110 101 770.00CH ETH-782

PTO-1556
(5/87)

[redacted]

07/838511

Case Docket No.: ETH-782

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of

Inventor: Alastair Hunter et al.

For : STERILIZED HETEROGENEOUS BRAIDS

Enclosed are:

[X] Three (3) sheets of drawings (Formal).

[X] Two signed Declarations and Powers of Attorney.

[X] Two assignments of the invention to Ethicon, Inc.

[ ] A certified copy of a ________________ application.

[ ] Associate Power of Attorney.

[X] Information Disclosure Statement.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $690.00
TOTAL CLAIMS	24 - 20 =	4	x 20.00	$ 80.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 72.00	$ 000.00
MULTIPLE DEPENDENT CLAIMS	no		$220.00	$ 000.00
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			TOTAL FEES	$ 810.00

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Matthew Goodwin
Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2791
February 19, 1992

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MAILED FEBRUARY 19, 1992

DOCKET NO. ETH-782

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Alastair Hunter et al.

For : STERILIZED HETEROGENEOUS BRAIDS

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"Express Mail" mailing number HB346860118

Date of Deposit February 19, 1992

I hereby certify that this complete application, including specification pages, claims, formal drawings, Information Disclosure Statement, PTO-Form 1449, Assignments, and Declarations and Powers of Attorney, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patent and Trademarks, Washington, D.C. 20231.

Matthew S. Goodwin
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Matthew Good
(Signature of person mailing paper or fee)

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[redacted]

#1 838511

TITLE OF THE INVENTION

STERILIZED HETEROGENEOUS BRAIDS

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BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

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MAILED FEBRUARY 19, 1992

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U.S. Patent 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Patent 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

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An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Patent 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

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More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Patent 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite

sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by Figure 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying

5

the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

Figure 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

Figure 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

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DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at

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least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Patent Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Patent Nos. 4,959,069 and 5,059,213.

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The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns,

respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle

of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below

about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of Figure 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of Figure 1 are dispensed upward

with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

4C In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. 4C In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 4C 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in Figure 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 4C 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using A from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

11

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing

12

stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Patent 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is

determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

C.L

EXAMPLES

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Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Patent 4,470,941.

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CONTROL I

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FIBER MATERIALS: An 8x0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

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PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each

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carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225 C°.

CONTROL II

<u>FIBER MATERIALS</u>: An 8x0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

<u>PROCESSING:</u> The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

<u>FIBER MATERIALS</u>: An 8x0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

<u>PROCESSING</u>: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm.

The braid is scoured and hot stretched per the conditions described in CONTROL I.

CL

EXAMPLE II

PB

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PB

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

CL

PRIOR ART I

PB

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PB

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300 C° and for a longer residence time to facilitate melting of the PET fibers.

P

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gmXcm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.87			0.0966	

TI 7CX

PS

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

STiI

$$P_c = (Vf_a)\ (P_a) + (Vf_b)\ (P_b)$$

PSPSH

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in Figure 2, which shows a plot of tensile strength versus

17

volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in Figure 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the <u>bending moment-radius of curvature</u> plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

I

FB

U.S. Patent 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and Figure 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

B

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Cri

WHAT IS CLAIMED IS:

1. A heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and:

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

2. The heterogeneous braid of claim 1 wherein the first and second fiber-forming materials are nonmetallic.

3. The heterogeneous braid of claim 2 wherein the first and second fiber-forming materials are synthetic fiber-forming polymers.

4. The heterogeneous braid of claim 3 wherein the synthetic fiber-forming polymers are bioabsorbable.

5. The heterogeneous braid of claim 4 wherein the bioabsorbable polymers are derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactide, p-dioxanone, ε-caprolactone, trimethylene carbonate, and mixtures thereof.

6. The heterogeneous braid of claim 3 wherein the fiber-forming polymers are nonabsorbable.

19

~~7~~ 3. The ~~heterogeneous braid~~ surgical suture of claim ~~6~~ 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

~~8~~ 4. The ~~heterogeneous braid~~ surgical suture of claim ~~7~~ 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

~~9. The heterogeneous braid of claim 8 wherein the first set of yarns is PTFE, FEP, PFA, PVDF, PETFE, PP or PE.~~

~~10~~ 5. The ~~heterogeneous braid~~ surgical suture of claim ~~8~~ 4 wherein the first set of yarns is PTFE.

~~11~~ 6. The ~~heterogeneous braid~~ surgical suture of claim ~~10~~ 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

~~12~~ 7. The ~~heterogeneous braid~~ surgical suture of claim ~~11~~ 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

~~13. The heterogeneous braid of claim 12 wherein the second set of yarns is PET, nylon or aramid.~~

~~14~~ 8. The ~~heterogeneous braid~~ surgical suture of claim ~~13~~ 1 wherein the second set of yarns is PET.

~~15. The heterogeneous braid of claim 14 wherein each yarn from the first set is in direct intertwining contact with a yarn from the second set.~~

~~16. The heterogeneous braid of claim 15 wherein the braid encloses a core of longitudinally extending yarns.~~

~~17. The heterogeneous braid of claim 16 wherein the longitudinally extending yarns are PET.~~

9 ~~18~~. The surgical suture ~~heterogeneous braid~~ of claim ~~17~~ 14 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10 ~~19~~. The surgical suture ~~heterogeneous braid~~ of claim 9 ~~18~~ wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11 ~~20~~. The surgical suture ~~heterogeneous braid~~ of claim ~~21~~ 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

~~21. A surgical suture comprising the heterogeneous braid of claim 1.~~

~~22. A surgical suture comprising the heterogeneous braid of claim 19.~~

2 ~~23~~. The surgical suture of claim 1 ~~21~~ wherein the suture is attached to a needle.

12 ~~24~~. The surgical suture of claim ~~22~~ 14 8 wherein the suture is attached to a needle.

ETH-782

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07/838,511

ABSTRACT

SA Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

PA Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

E71

[redacted]

DOCKET NO. ETH-838511

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

(check one) [X] is attached hereto.

[ ] was filed on as

Application Serial No.

and was amended on . (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
		Day/Mo./Year	[ ] YES [ ] NO
		Day/Mo./Year	[ ] YES [ ] NO
		Day/Mo./Year	[ ] YES [ ] NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (patented, pending, abandoned)
Application Serial No.	Filing Date	Status (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Robert L. Minier (Reg. #20,083), Audley A. Ciamporcero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Jason Lipow (Reg. #25,509), and Matthew S. Goodwin (Reg. #32,839), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

5

Address all telephone calls to Matthew S. Goodwin at telephone no. (908) 524-2791.

Address all correspondence to Robert L. Minier, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1

Inventor's Signature: Alastair M. Hunter

Full Name of Sole or First Inventor: Alastair W. Hunter

Date: 2/18/92

Citizenship: U.S.A.
Residence: 516 Spring Valley Drive, Bridgewater, New Jersey 08807 NJ
Post Office Address: Same as above

2

Inventor's Signature: Dennis D. Jamiolkowski

Full Name of Second Joint Inventor, If Any: Dennis D. Jamiolkowski

Date: 2/18/92

Citizenship: U.S.A.
Residence: 20 Fawnridge Drive, Long Valley, New Jersey 07853 NJ
Post Office Address: Same as above

#3

Inventor's Signature: Arthur Taylor Jr.

Full Name of Third Joint Inventor, If Any: Arthur Taylor, Jr.

Date: 2/18/92

Citizenship: U.S.A.
Residence: 1217 East Second Street, Plainfield, New Jersey 07062 NJ
Post Office Address: Same as above

(Supply similar information and signature for fourth and subsequent joint inventors.)

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Rev.

07 838511

DOCKET NO. [redacted]

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

(check one) [X] is attached hereto.

[ ] was filed on as

Application Serial No.

and was amended on .
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

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I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

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		Day/Mo./Year	[ ] YES [ ] NO
		Day/Mo./Year	[ ] YES [ ] NO
		Day/Mo./Year	[ ] YES [ ] NO

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Application Serial No.	Filing Date	Status (patented, pending, abandoned)
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H Inventor's Signature: Full Name of Sole or First Inventor

Mark Steckel

Date: 2/17/92

Citizenship: U.S.A.
Residence: 8919 Farmdale Way, Maineville, Ohio 45039 OH
Post Office Address: Same as above

Inventor's Signature: Full Name of Second Joint Inventor, If Any

Date:

Citizenship:
Residence:
Post Office Address:

Inventor's Signature: Full Name of Third Joint Inventor, If Any

Date:

Citizenship:
Residence:
Post Office Address:

(Supply similar information and signature for fourth and subsequent joint inventors.)

[redacted]

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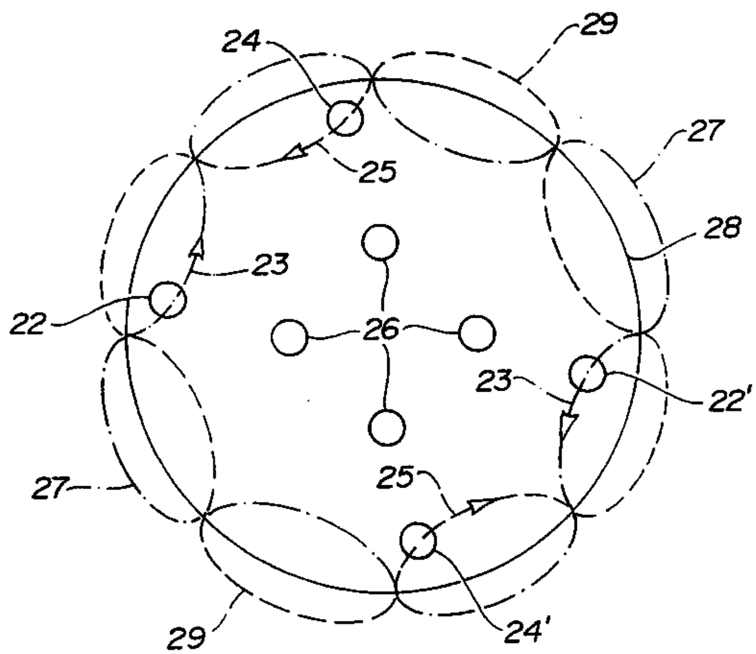
FIG-1



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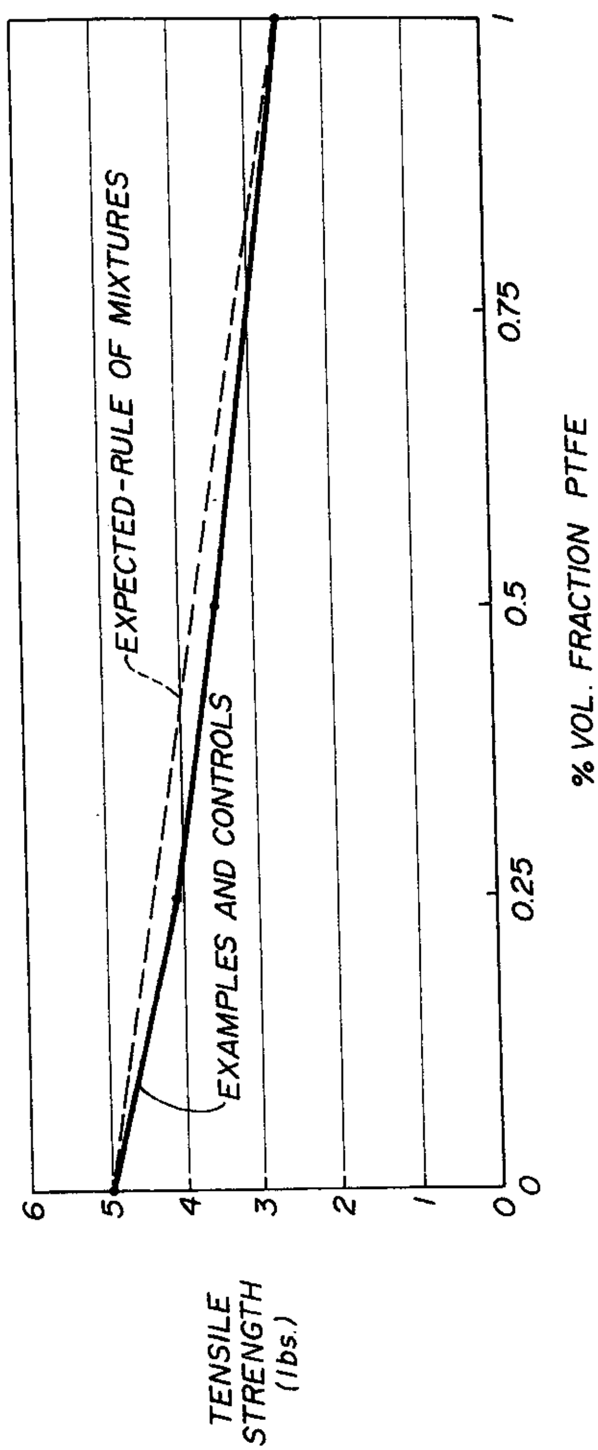
[redacted]

FIG-2



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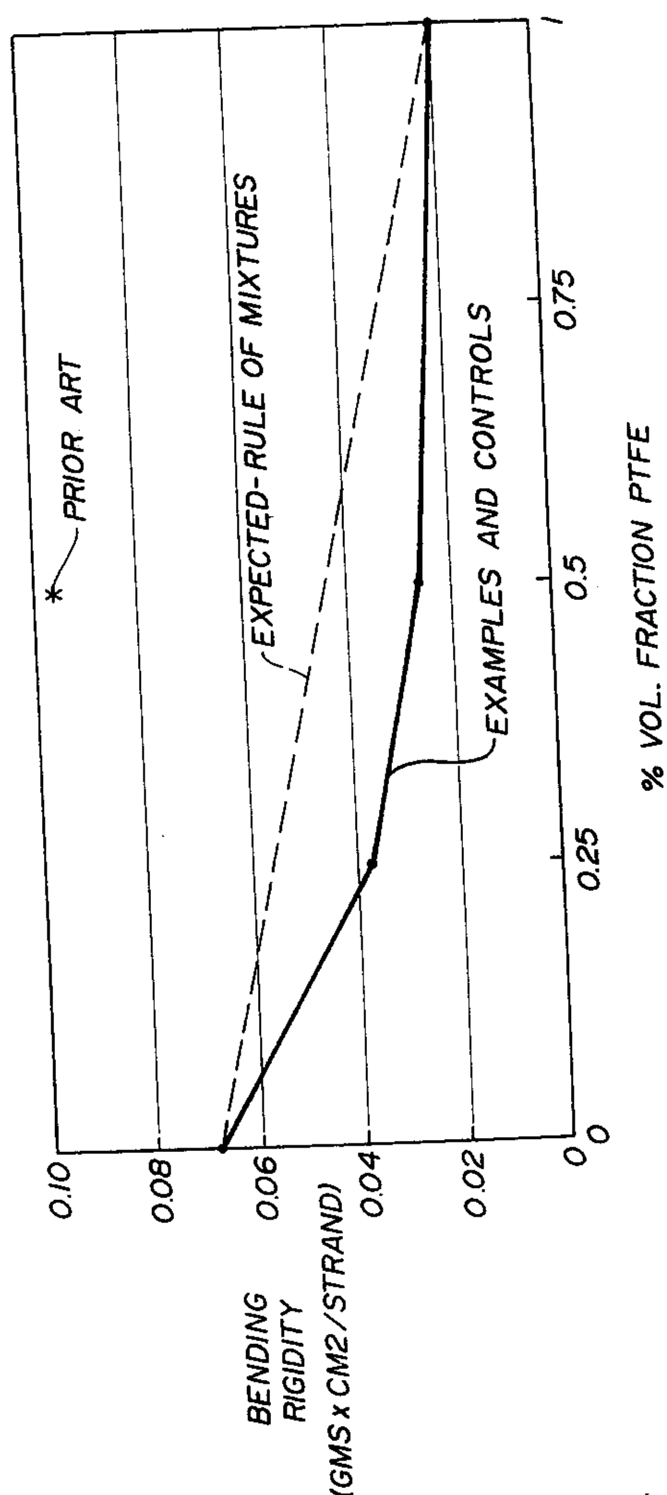

FIG-3

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96)

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FIG-1

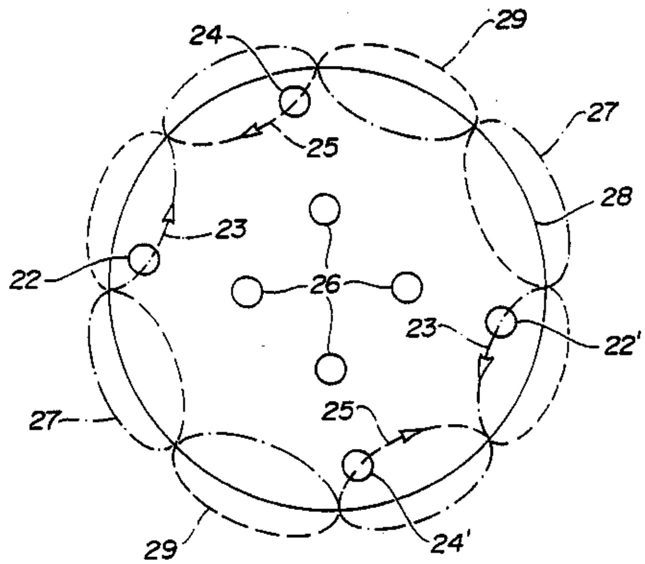

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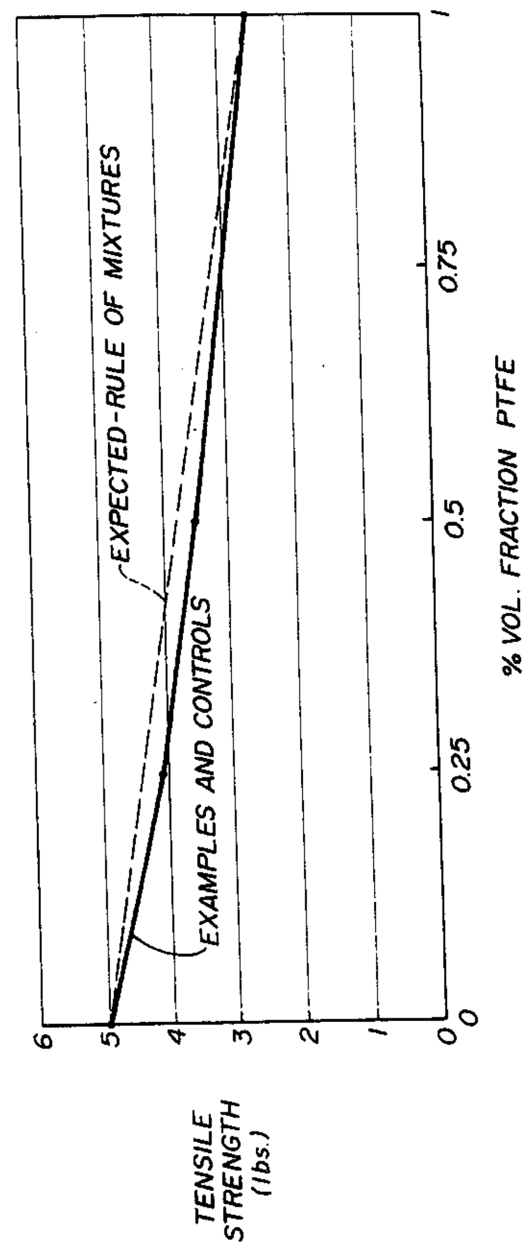
FIG-2



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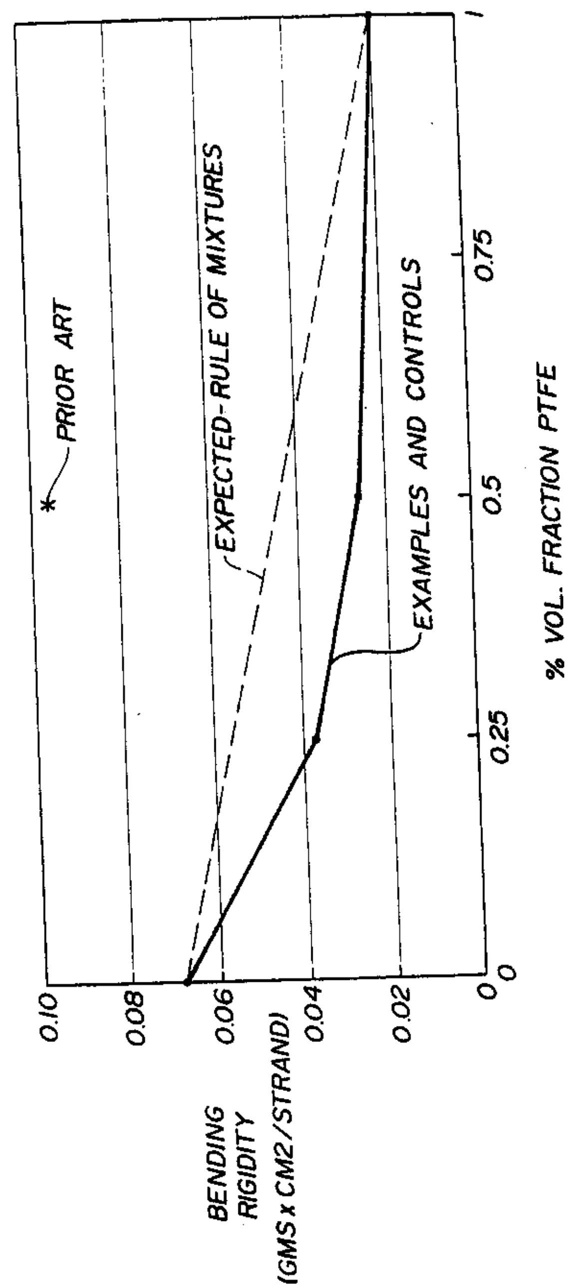

FIG-3

HERMES DECLARATION
EXHIBIT 15 – PART 2 OF 8

US005314446A

United States Patent [19]

Hunter et al.

[11] **Patent Number: 5,314,446**

[45] **Date of Patent: May 24, 1994**

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] Int. Cl.[5] **D04C 1/00**

[52] U.S. Cl. **606/231; 606/228;** 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
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3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
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WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	.
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

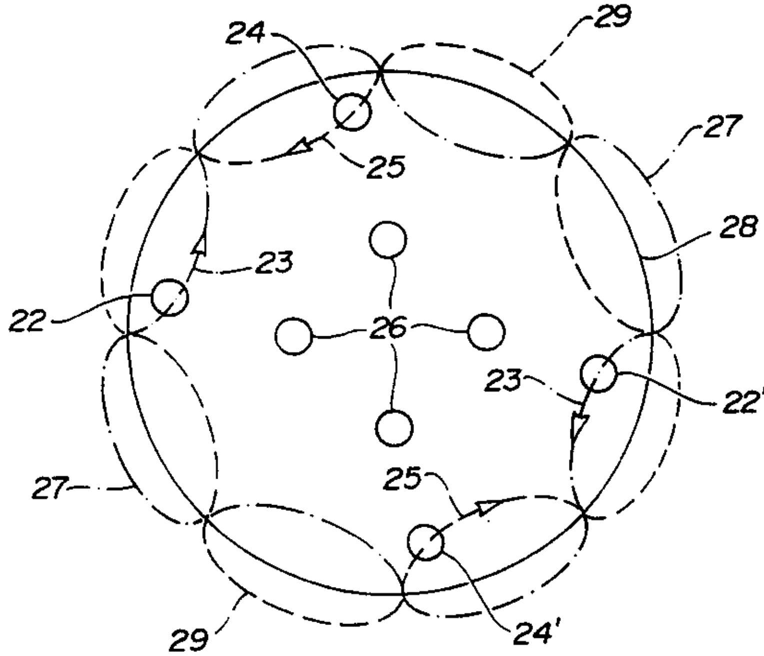


FIG-2

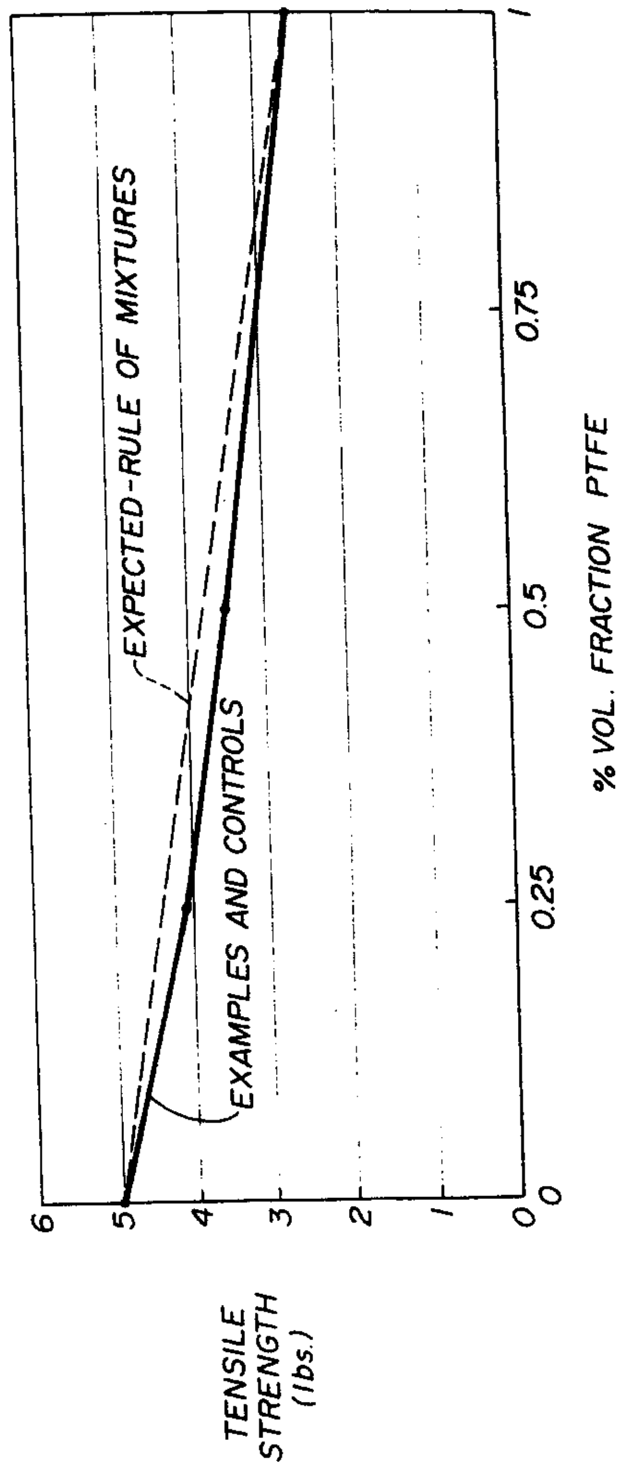
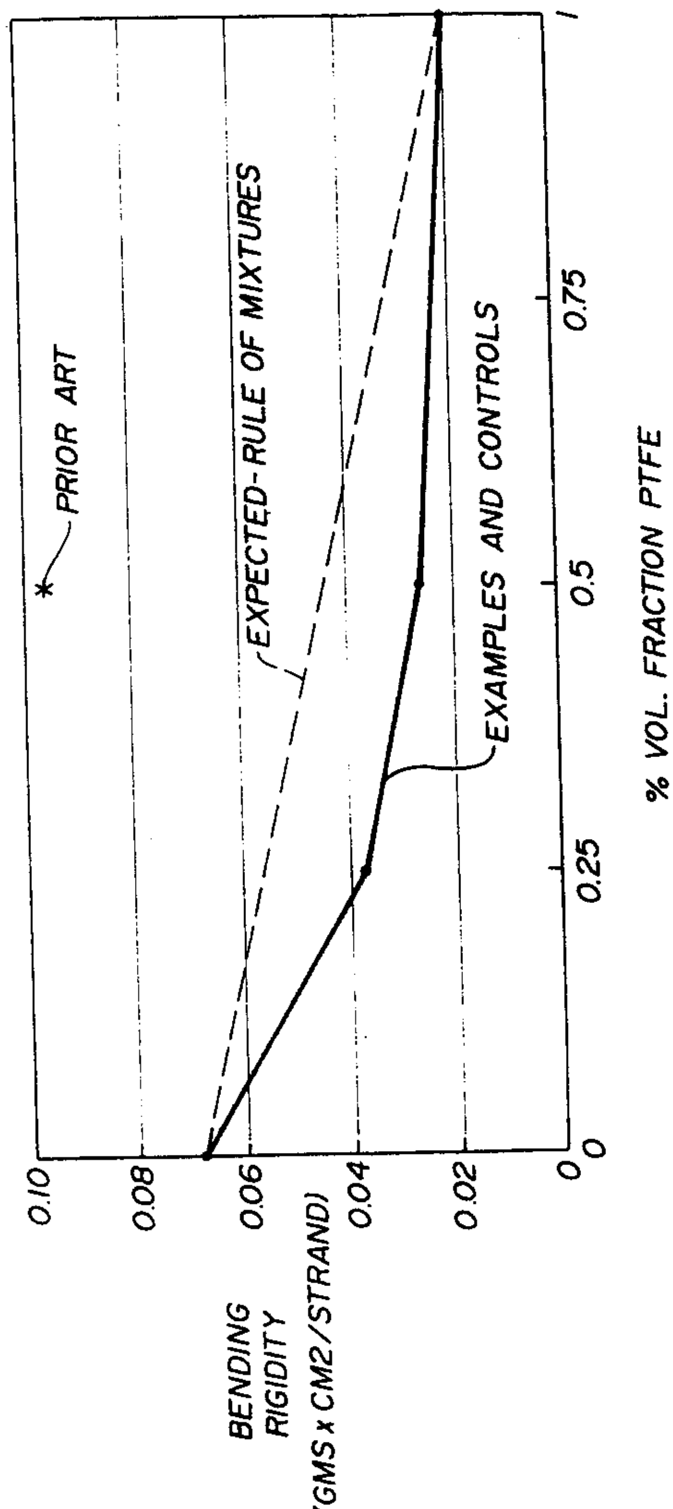

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000057

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000058

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000059

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a)(P_a) + (Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000060

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000061

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
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MAIL ROOM FEB 19 1992 PAT. & TRADEMARK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: Art Unit: #2

Filed : Examiner:

For : STERILIZED HETEROGENEOUS BRAIDS

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The following references are discussed in the Background of the Invention:

U.S. Patent 3,942,532 (Hunter, et al., issued March 9, 1976).

U.S. Patent 4,624,256 (Messier et al., issued November 25, 1986).

U.S. Patent 3,527,650 (Block, A., issued September 8, 1970).

U.S. Patent 4,470,941 (Kurtz, L., issued September 11, 1984).

WO 86/00020 (Kurtz et al., issued January 3, 1986).

The following additional references may be relevant to the examination of the above-identified application:

U.S. Patent 3,187,752 (Glick, A., issued June 8, 1965), discloses a tightly braided nonabsorbable suture coated with a polymeric silicone.

U.S. Patent 4,043,344 (Landi et al., issued August 23, 1977), discloses a nonabsorbable suture coated with a polyoxyethylene-polyoxypropylene copolymer.

VIA EXPRESS MAIL NO. HB346860118
~~MAILED~~ FEBRUARY 19, 1992

U.S. Patent 4,047,533 (Periaccante et al., issued September 13, 1977), discloses an absorbable suture coated with a polyoxyethylene-polyoxypropylene copolymer.

U.S. Patent 4,946,467 (Ohi et al., issued August 7, 1990), discloses a suture having a core of one synthetic fiber material and a covering sheath of silk strands.

U.K. Patent Application GB 2 218 312A, discloses a fishing line of braided construction, some braid filaments being composed of polythene and other filaments composed of polyester and/or nylon.

German Patent DE 2949920, discloses a suture having a core of fibers composed of platinum or gold, and a braided sheath of fibers composed of polytetrafluoroethylene.

A completed Form PTO-1449 and a copy of each cited reference is attached herewith.

Respectfully submitted,

Matthew S. Goodwin
Reg. No. 32,839
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08903
(908) 524-2791
February 19, 1992

United States Patent [19]
Hunter et al.

[11] 3,942,532
[45] Mar. 9, 1976

[54] BRAIDED SUTURE

[75] Inventors: Alastair Wilson Hunter; Darrell R. Thompson, both of Somerville, N.J.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[22] Filed: Aug. 15, 1974

[21] Appl. No.: 497,596

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 303,588, Nov. 3, 1972, abandoned.

[52] U.S. Cl. 128/335.5; 428/375
[51] Int. Cl.[2] A61L 17/00
[58] Field of Search 128/335.5; 161/175, 176; 117/139.5 F, 161 R

[56] References Cited

UNITED STATES PATENTS

3,527,650	9/1970	Block	128/335.5 X
3,694,257	9/1972	Dumont	117/139.5 F
3,754,069	8/1973	Adams et al.	128/335.5 X
3,776,766	12/1973	Smerz et al.	117/139.5 F X
3,839,524	10/1974	Adams et al.	128/335.5 X

Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] ABSTRACT

The tie-down characteristics of braided sutures are improved by applying to the surface thereof a polymeric ester of a dibasic acid and a glycol.

16 Claims, 3 Drawing Figures

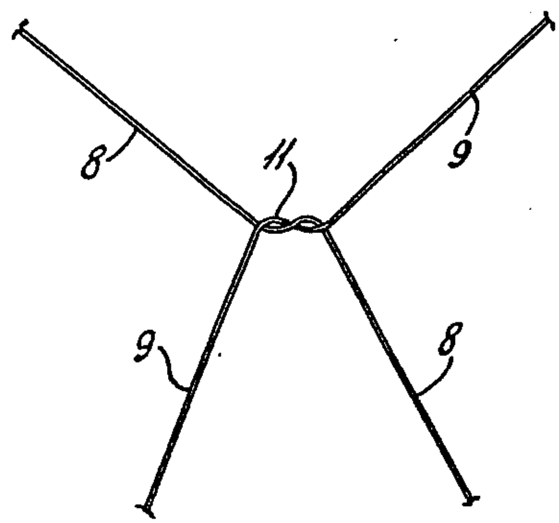


Fig. 1.

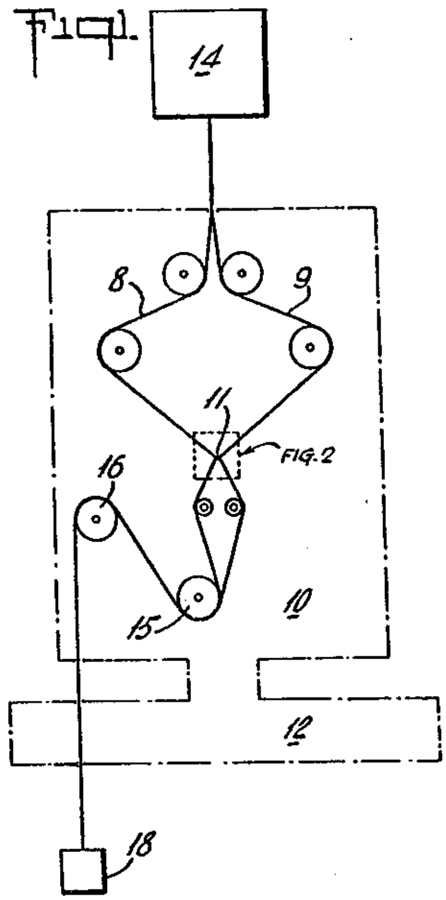


Fig. 2.

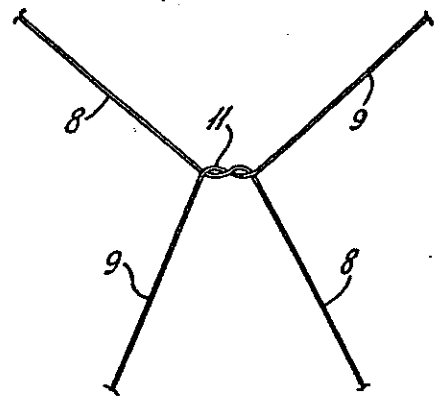
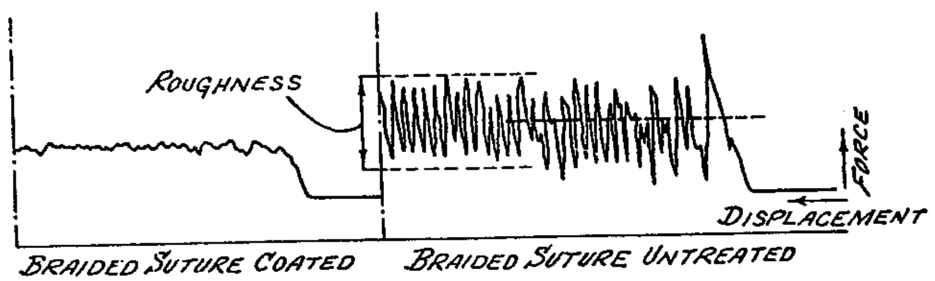


Fig. 3.



BRAIDED SUTURE

BACKGROUND OF THE INVENTION

This application is a continuation-in-part of my co-pending U.S. application Ser. No. 303,588, filed Nov. 3, 1972 now abandoned.

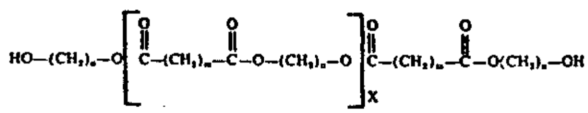
The present invention relates to surgical sutures and more specifically to multifilament sutures. Braided polyester multifilament sutures have been used by many surgeons for their strength and lack of tissue reactivity. Other surgeons prefer to use waxed silk when a non-absorbable suture is required because of its excellent hand, ease of knotting, and ease of passage through tissue.

An important characteristic of sutures in deep wound surgery is the ease of sliding a single throw knot down the suture into place. This behavior, sometimes referred to as the "tie-down performance" may be evaluated subjectively by tying a suture around a suitable mandrel. A single throw knot is formed and while pulling on the two free ends, the knot is forced to slide along the suture. The roughness or smoothness of this sliding action is an important criterion of performance.

Uncoated braids such as a braided polyethylene terephthalate suture give a very rough, jerky behavior while sutures coated with TEFLON, as described in U.S. Pat. No. 3,527,650 and wax-coated braided silk sutures are very smooth. Fortunately, the roughness or smoothness of tie-down can be measured and assigned a numerical value that will enable one to predict performance in the hands of the surgeon without reliance upon the subjective test referred to in the preceding paragraph. A method of using an INSTRON Universal Testing Instrument to determine tie-down performance is described below.

The present invention is directed to improving the tie-down characteristics of a braided suture by applying a surface coating of a non-toxic and physiologically inert polymer that does not adversely affect the hand or tensile properties of the suture.

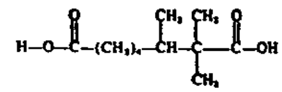
It has now been discovered that the tie-down performance of braided, twisted, or covered multifilament sutures may be improved (the roughness decreased) by applying to the surface thereof polyesters derived from the polymerization of lactones or obtained by esterifying low molecular weight glycols with a dimeric acid. Preferred coating compositions are polyesters characterized by a melting point above room temperature and have the formula:



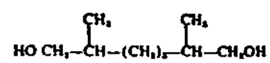
wherein n is an integer larger than 1 and smaller than 13, m is an integer larger than 1 and smaller than 9 and X is the degree of polymerization. Thus, stoichiometric quantities of succinic, glutaric, adipic, pimelic, suberic, azelaic, sebacic acid, or mixtures thereof may be condensed with ethylene glycol, propylene glycol, butanediol, pentanediol, hexanediol, nonanediol, decanediol, undecanediol, dodecanediol, or mixtures thereof to obtain a polyester suitable for application as a surface coating. Polyesters of the above formula having a molecular weight in the range of approximately 1,000 to

15,000 and characterized by having at least two carbon atoms between the ester linkages in the polymer chain have been found to give the best lubricant and handling properties on silk and polyester sutures. Particularly preferred polyesters are those derived from 1,4-butanediol (n=4) and adipic acid (m=4) having a molecular weight of 2,000–3,000.

It will be understood that branched chain acids such as α,α,β-trimethylsuberic acid having the formula:

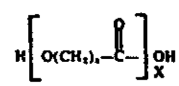


3,7-dimethyloctadienoic acid; 1,4-cyclohexanecarboxylic acid; mesatonic acid; β,β-dimethyl glutaric acid; and dimer acid; and branched chain diols such as diisononyl glycol having the formula:

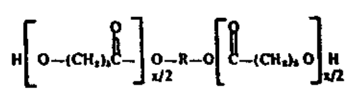


and glycols having a secondary hydroxyl group such as 1,2-propylene glycol may be added to the reaction mixture in small amounts as comonomers to produce polyesters suitable as coating materials that have a melting point above room temperature. The addition of larger amounts of such comonomers to the reaction mixture will result in low melting polyesters that are unsuitable for use in the present invention.

Polyesters that are useful in the manufacture of coated sutures in accordance with the present invention may also be prepared by polymerizing lactones. Such polyesters are characterized by a melting point above room temperature, and have the formula:



wherein n is an integer larger than 2 and X is the degree of polymerization. Particularly preferred is the polyester characterized by a molecular weight of about 2,000 obtained by polymerizing ϵ-caprolactones in the presence of a poly-methylenediol and having the formula:



wherein R is a polymethylene group derived from the poly-methylenediol and x is the degree of polymerization.

The polyester coating compositions described above are non-toxic and may be applied to the multifilament suture from solution. The multifilament suture may be

of braided, twisted, or covered construction. The construction of a covered suture is described in U.S. Pat. No. 3,791,388. The suture is then air dried to remove solvent and form a continuous surface coating.

The amount of the polyester coating composition applied to the suture may be varied depending upon the suture size and composition. Thus, the surface coating on a size 7/0 braided polyester suture may amount to from about 5 percent to as much as 7 percent of the weight of the suture. Sutures of larger size (size 5/0 – 5) require a smaller amount of the polyester coating composition (about 0.4 percent to 1 percent based upon the weight of the suture).

The surface coating composition (0.4 percent to about 7 percent based on suture weight) has no detrimental effect on tensile strength or stability. While the application of an excess of the surface coating composition has an effect on lubricity, it may detract from other physical properties of the suture, particularly knot stability.

A numerical value may be assigned to the tie-down performance of any braided suture when tested in accordance with the following procedure. In describing the test for tie-down performance reference is made to the accompanying drawings wherein:

FIG. 1 is a diagrammatic representation of an INSTRON Tester and shows two braided suture strands in position for testing;

FIG. 2 is an enlarged perspective view of the single throw knot illustrated in FIG. 1;

FIG. 3 is a reproduction of the tracing of an oscillographic recorder.

All tie-down measurements reported in the tables are made on a Table-Model INSTRON Tensile Tester using a Type B tension cell, full-scale range 100 to 2,000 grams. The INSTRON instrument is manufactured by the Instron Corporation of Canton, Massachusetts. A high-speed SANBORN Oscillographic Recorder (Model 7702A, manufactured by Hewlett-Packard, Waltham, Massachusetts) is substituted for the standard INSTRON Recorder which would be too slow to follow the rapid changes in force that result as the sutures under test slide against each other. A high-gain DC Amplifier (Hewlett-Packard Model 8803A, manufactured by Hewlett-Packard, Waltham Division, Waltham, Massachusetts) is used to interface this recorder with the INSTRON Transducer and a low-voltage DC power supply is provided to excite the transducer. The measurements are made in an air-conditioned laboratory at 72°F. and 50 percent relative humidity. To hold the specimen suture strands, a line contact jaw is used. The INSTRON machine is operated at a cross-head speed of 50 inches per minute and the chart speed of the oscillographic recorder is 20 millimeters per second.

Subjective tests for tie-down involved the suture configuration 11 shown in FIG. 2 (a single throw knot). The same configuration is produced by a pulley arrangement that is supported by a steel plate 10 shown in FIG. 1. The steel plate is attached to the cross-head 12 of the INSTRON Tester.

To perform tie-down measurements, two strands 8 and 9 of the same suture are attached at one end to the B cell transducer 14 of an INSTRON Tester. The sutures are threaded through the pulley arrangement as shown in FIGS. 1 and 2. The other end of the suture strands are brought together, passed around the pulleys 15 and 16, and attached together to a weight 18 which provides tension similar to that applied in a subjective test. A weight of 2.5 pounds is used in the standard procedure.

FIG. 3 shows actual recorder traces for a braided polyethylene terephthalate suture before and after coating with a polymer to improve tie-down performance. The roughness values are measured along the ordinate and throughout the specification and examples are recorded in pounds (roughness). When relatively smooth samples are compared, the amplitude of the oscillographic recorder can be increased by a factor of 20.

The present invention will be further illustrated by the following examples which illustrate preferred embodiments of the inventive idea.

EXAMPLE I

A condensation polymer is prepared by reacting 42.5 weight percent of 1,4-butanediol with 57.5 weight percent of adipic acid. The polymer so obtained is a firm, waxy solid having a viscosity of 1475 cps. at 60°C., a molecular weight of 2150, an acid number of 1.7, and a hydroxyl number of 52.1.

The polyester prepared as described in the preceding paragraph (4.84 parts by weight) is dissolved in 95.16 parts by weight of toluene and the solution is applied to a braided, size 2/0 polyethylene terephthalate suture strand using an ATLAB Yarn Finish Applicator manufactured by Precision Machine & Development Company, P.O. Box 645, New Castle, Delaware. The braid is coated under the following conditions:

Speed of Yarn	30 feet per minute
Hypodermic Syringe Size	30 cc.
Motor Drive Rate	10 r.p.m.
Hysteresis Tension	5 pounds.

The coated, braided strand is dried in forced air at 70°–80°F. to evaporate the solvent and is then collected on a take-up drum. No curing of the adipic ester is required. The coating is continuous over the entire surface of the suture and amounts to 1 percent by weight (based on the weight of the untreated suture). The coated braid is sterilized by exposure to cobalt-60 irradiation without significant loss of straight tensile strength or knot strength. The physical characteristics of the braided polyethylene terephthalate suture before and after coating are summarized in Table I.

TABLE I

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Tensile Strength		
Non-Sterile	100,200 p.s.i.	99,100 p.s.i.
Sterile	99,400 p.s.i.	98,800 p.s.i.
Knot Strength		
Non-Sterile	53,900 p.s.i.	53,500 p.s.i.
Sterile	52,100 p.s.i.	55,000 p.s.i.

TABLE 1-continued

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Roughness	3.67 lbs.	0.31 lbs.

Similar results are obtained when the polyester resin described in this Example is used to coat braided silk, cotton, and collagen sutures. However, higher levels of coating solids should be used for the hydrophilic substrates such as cotton and silk. The coated sutures made according to this example have excellent knot holding properties.

EXAMPLE II

A linear polymer of ε-caprolactone characterized by an average molecular weight of about 2,000 and having the structural formula:

$$\left[H\ \ O(CH_2)_5-\overset{\displaystyle O}{\overset{\|}{C}}\right]_x O-R-O\left[\overset{\displaystyle O}{\overset{\|}{C}}-(CH_2)_5-O\right]_x H$$

wherein R is a polymethylene group derived from a polymethylenediol and x represents the degree of polymerization, was purchased from the Union Carbide Corporation, Chemical Division, 270 Park Avenue, New York City, New York. This polycaprolactone has a molecular weight of about 2,000 and is sold under the trade name NIAX POLYOL D-560.

The polycaprolactone identified above was dissolved in toluene to obtain a 3.8 percent by weight solution. This solution is applied to a braided, size 2/0 polyethylene terephthalate suture strand using an ATLAB Yarn Finish Applicator. The braid is coated under the conditions as described in Example I above and dried in forced air at 75°F. The coated braid, after evaporation of the solvent is collected on a take-up drum. No curing of the polycaprolactone is required. The coating is continuous over the entire surface of the suture and amounts to 1 percent by weight (based on the weight of the untreated suture). The coated braid is sterilized by exposure to cobalt-60 irradiation without appreciable loss of straight tensile strength or knot strength. The physical characteristics of the braided polyethylene terephthalate suture before and after coating are summarized in Table 2.

TABLE 2

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Tensile Strength		
Non-Sterile	96,300 p.s.i.	92,000 p.s.i.
Sterile	95,100 p.s.i.	91,500 p.s.i.
Knot Strength		
Non-Sterile	53,900 p.s.i.	51,700 p.s.i.
Sterile	54,700 p.s.i.	51,700 p.s.i.
Roughness	2.77 lbs.	0.67 lbs.

Similar results are obtained when the polycaprolactone is used to coat braided silk, cotton, and collagen sutures of size 2/0 through 6/0. The polyesters of the present invention may also be used to coat absorbable synthetic sutures such as those described in U.S. Pat. No. 3,297,033 and 3,636,956 with a resulting improvement in tie-down characteristics.

What is claimed is:

1. A suture having improved tie-down performance comprising a multifilament, the outer surface of the multiflament being coated with from about 0.4 percent to about 7 percent based on suture weight of an aliphatic polyester that is a solid at room temperature; said polyester having from 2 carbon atoms to about 12 carbon atoms between the ester linkages in the polymer chain and said polyester having a molecular weight in the range of 1,000 to 15,000.

2. The suture of claim 1, characterized by a braided construction.

3. The suture of claim 1, characterized by a twisted construction.

4. The suture of claim 1, characterized by a covered construction.

5. The multifilament suture of claim 1, wherein the polyester has the formula:

$$HO-(CH_2)_n-O\left[\overset{\displaystyle O}{\overset{\|}{C}}(CH_2)_m-\overset{\displaystyle O}{\overset{\|}{C}}-O-(CH_2)_n-O\right]_X\overset{\displaystyle O}{\overset{\|}{C}}-(CH_2)_m-\overset{\displaystyle O}{\overset{\|}{C}}-O(CH_2)_n-OH$$

wherein n is an integer larger than 1 and smaller than 13, m is an integer larger than 1 and smaller than 9 and X is the degree of polymerization.

6. The multifilament suture of claim 1, wherein the polyester has the formula:

$$H\left[O(CH_2)_5\overset{\displaystyle O}{\overset{\|}{C}}\right]-ORO-\left[\overset{\displaystyle O}{\overset{\|}{C}}-(CH_2)_5O\right]_{x/2}H$$

wherein R is a polymethylene group and X represents the degree of polymerization.

7. The multifilament suture of claim 1, wherein the polyester is a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000–3,000.

8. The suture of claim 7, wherein said multifilament is a silk multifilament and the polyester coating

amounts to about 5 p... ...nt of the weight of the untreated suture.

9. The suture of claim 7, wherein said multifilament is a polyethylene terephthalate multifilament, and the polyester coating amounts to about 1 percent of the weight of the untreated suture.

10. The multifilament suture of cliam 6, wherein the polyester coating has a molecular weight of about 2,000.

11. The suture of claim 10, wherein said multifilament is a polyethylene terephthalate multifilament and the polyester coating amounts to about 1 percent of the weight of the untreated suture.

12. The su...e of claim 10, wherein said multifilament is a silk multifilament and the polyester coating amounts to about 5 percent of the weight of the untreated suture.

13. The multifilament suture of claim 1, characterized by a roughness of less than 1 pound.

14. The multifilament suture of claim 2, characterized by a roughness of less than 1 pound.

15. The multifilament suture of claim 3, characterized by a roughness of less than 1 pound.

16. The multifilament suture of claim 4, characterized by a roughness of less than 1 pound.

* * * * *

United States Patent [19]
Messier et al.

[11] Patent Number: 4,624,256
[45] Date of Patent: Nov. 25, 1986

[54] CAPROLACTONE POLYMERS FOR SUTURE COATING

[75] Inventors: Kenneth A. Messier, Jewett City; Joseph D. Rhum, Old Lyme, both of Conn.

[73] Assignee: Pfizer Hospital Products Group, Inc., New York, N.Y.

[21] Appl. No.: 774,636

[22] Filed: Sep. 11, 1985

[51] Int. Cl.[4] A61L 17/00
[52] U.S. Cl. 128/335.5
[58] Field of Search 128/335.5

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Primary Examiner—Gregory E. McNeill
Attorney, Agent, or Firm—Charles J. Knuth; Peter C. Richardson; Gezina Holtrust

[57] ABSTRACT

High molecular weight caprolactone polymers are coated on surgical sutures to improve suture properties such as smooth surface, single knot slipdown, two throw knot slipdown for repositioning, and three throw knot security.

8 Claims, No Drawings

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000071

CAPROLACTONE POLYMERS FOR SUTURE COATING

BACKGROUND OF THE INVENTION

The invention relates to surgical sutures comprising a braided multifilament of a biocompatible material coated with a lubricating agent. More particularly, the invention relates to sutures coated with high molecular weight polycaprolactone or a high molecular weight copolymer of at least 90% by weight of caprolactone.

Coating of braided sutures with lubricating agents to improve knot slipdown properties is known in the art. For instance, U.S. Pat. No. 4,080,969 discloses coating braided polyglycolic acid filaments with diglycolate polyesters. U.S. Pat. No. 4,027,676 provides a coating for sutures comprising a bioabsorbable film-forming polymer, the bioabsorbable lubricant polyalkylene glycol and a hydrophobic material. U.S. Pat. No. 3,867,190 relates to polyglycolic acid sutures coated with a copolymer of lactic and glycolic acid. This patent also mentions incorporation of caprolactone in glycolide sutures. The formed copolymer contains not more than 15% by weight of caprolactone. Use of such copolymer in coating of sutures is not suggested.

U.S. Pat. No. 3,942,532 describes polyester multifilament sutures coated with polycaprolactone Niax Polyol D-560 having a low molecular weight of about 2,000 and a melt viscosity at 60° C. of 500 centipoise.

It is an object of the invention to provide a suture having a smooth surface, good single knot slipdown, two throw knot slipdown for repositioning, and three throw knot security.

SUMMARY OF THE INVENTION

In accordance with the invention, there is provided a surgical suture of a braided multifilament biocompatible, bioabsorbable material coated with a lubricating agent selected from the group consisting of high molecular weight polycaprolactone, a high molecular weight copolymer derived from at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said polycaprolactone or said copolymer and up to 50% by weight of another biodegradable lubricating agent, based on the combined weights of the lubricating agents. The homopolymer or copolymer of caprolactone has a melt viscosity at 60° C. of at least about 50,000 centipoise (cps) or is a solid.

Generally, the lubricating agent or agents are present in an amount of about 0.5 to 10% by weight based on the suture.

The invention also provides for a needled surgical suture wherein a novel coated suture as described above is threaded through or fitted with a surgical needle, and a surgical suture package comprising a sterile enclosure containing a sterile needled coated surgical suture as previously described.

DETAILED DESCRIPTION OF THE INVENTION

According to the invention, any conventional bioabsorbable suture material may be used. Sutures must be biocompatible such that they do not cause any adverse reactions in living tissue. The sutures of the invention are bioabsorbable such that they are slowly absorbed in living tissue. Examples of suitable bioabsorbable suture materials are collagen, poly(glycolic acid), poly(lactic

acid), poly(hydroxybutyric acid), chitosan, chitin, carboxymethylcellulose etc. Preferably, the suture is made of poly(glycolic acid) or a glycolic acid copolymer containing at least 85% glycolic acid units.

The primary lubricating agent of the invention is high molecular weight polycaprolactone or a high molecular weight copolymer of at least 90% by weight of caprolactone and at most 10% by weight of another biodegradable monomer. Examples of such biodegradable monomers are glycolic acid, a glycolide, lactic acid, a lactide, p-dioxanone, valerolactone and other lactones derived from linear aliphatic hydroxycarboxylic acids, α-hydroxybutyric acid, ethylene carbonate, ethylene oxide, propylene oxide, propylene carbonate, malic acid ester lactones, succinic acid, adipic acid and other linear aliphatic dicarboxylic acids, and linear aliphatic diols such as butanediol and hexanediol.

High molecular weight polycaprolactone may be made by conventional methods for the polymerization of ε-caprolactone. Suitable polycaprolactones are commercially available, e.g. PCL-300 and PCL-700 of Union Carbide Corporation, also known by the brand names Tone P-300 and Tone P-700, respectively, having weight average molecular weights of about 15,000 and about 40,000, respectively, as reported by the manufacturer. Copolymers of caprolactone and another monomer may be made by conventional polymerization techniques, e.g. as described in U.S. Pat. No. 4,190,720.

When reference is made hereafter to polycaprolactone, this will include the above-described copolymers of caprolactone containing 10% or less of a biodegradable comonomer.

The high molecular weight polycaprolactone is applied to the multifilament suture generally from a solution in a solvent for polycaprolactone such as methylene chloride. Other known solvents for polycaprolactone may be used such as carbon tetrachloride, chloroform, ethyl acetate, cyclohexanone, methyl ethyl ketone, toluene, and xylene. The concentration of the polycaprolactone in the solvent may range from 1 to 10% by weight based on the solvent. Generally, about 5 g commercially available polycaprolactone per 100 ml of solvent is used. The preferred concentration will provide a readily flowable composition the solvent of which is not difficult to evaporate after the coating is applied, and will deposit the desired amount of polycaprolactone on the suture.

The sutures are immersed in the coating solution for 0.1 to 10 minutes, preferably about 0.2-3 minutes, and air dried at room temperature or, if desired, at slightly higher temperatures. The immersion may be carried out by batch dipping a skein or by continuously passing a continuous length of yarn through the coating solution.

The primary lubricating agent, high molecular weight polycaprolactone, may be mixed with other lubricating agents in an amount of up to 50% by weight of the combined lubricating agents. Examples of such other lubricating agents are poly(ethylene oxide), partially oxidized polyethylene wax, N,N'-ethylene diamine bis-stearamide, C_{10}–C_{30} fatty acid esters of sterols such as cholesterol and lanosterol, and polyalkylene glycols such as a copolymer of ethylene glycol and propylene glycol.

The coating composition may also contain other components for other purposes including dyes, stabilizers against oxidation or degradation caused by radiation, antibiotics, antiseptics, analgesics, anesthetics, anti-

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000072

inflammatory agents, growth or healing promoting agents and other pharmaceutically active ingredients.

Polycaprolactone is known to be a non-toxic material that degrades slowly in living tissue to form an innocuous metabolizable intermediate.

The following examples illustrate the invention. Examples 1-15 and 20 are comparative examples and Examples 16-19 are examples according to the invention.

EXAMPLES 1-19

Uncoated sutures of polyglycolic acid (18 inch long) were immersed in 100 ml of coating solution. The solvent, percentage by weight of coating material in solution, percentage coating by weight on the coated suture, and the size of the sutures are listed in Table 1.

The sutures were immersed in the coating solution for 2 to 3 minutes and air dried at room temperature. The percentage coating was calculated by weighing the suture on an analytical balance before and after coating and is given in Table 1 as percent of total weight of the coated suture. After air drying, the coated sutures were stored in a desiccator.

TABLE 1

Example	Suture size	Coating material	Solvent	% Coating material in solvent	% Coating on suture
1	2-0	PEO 8000	CH_2Cl_2	3	1.4
2	2-0	PGA powder	CH_2Cl_2	5	1.3
3	2-0	PEO 8000-PGA powder (5:1)	CH_2Cl_2	3.5	1.5
4	2-0	Plurocol P-4010	$CHCl_3$	3	1.0
5	3-0	PVP	$CHCl_3$	2	6.9
6	3-0	PVP	$CHCl_3$	2	1.7
7	3-0	PVA	H_2O	3	6.5
8	3-0	PEO 8000-calcium stearate (2:1)	CH_2Cl_2	3	3.4
9	2-0	Petrac 15	$CHCl_3$	5	3.5
10	2-0	Petrac 165	$CHCl_3$	5	2.9
11	2-0	PEG-100 stearate	CH_2Cl_2	5	4.4
12	2-0	PEG-40 stearate	CH_2Cl_2	5	3.9
13	2-0	Carnauba wax	$CHCl_3$	5	3.9
14	2-0	Kemamide W-40	$CHCl_3$	5	2.3
15	4-0	Cholesteryl palmitate	$CHCl_3$	5	2.5
16	1-0	PCL (Tone P300)	CH_2Cl_2	5	5.7
17	1-0	PCL (Tone P700)	CH_2Cl_2	5	4.1
18	1-0	PCL (Tone P700) Super Sterol Ester (1:1)	CH_2Cl_2	5	2.4
19	1-0	PCL (Tone P700) Super Sterol Ester (4:1)	CH_2Cl_2	5	3.1

The abbreviations and trademarks in Table 1 stand for the following:
PEO: poly(ethylene oxide)
PGA: poly(glycolic acid)
Plurocol P-4010: poly(propylene glycol)
PVA: poly(vinyl pyrrolidone)
Petrac 165: wax
Petrac 215: partially oxidized polyethylene wax (Petrochemicals Company Inc.)
PEG: poly(ethylene glycol)
Kemamide: N,N'—ethylene diamine bis-stearamide
PCL: polycaprolactone
Super Sterol Ester: cholesterol and lanosterol esters of a mixture of C_{10}—C_{30} fatty acids esters, supplied by CRODA Inc.

The melt viscosity of PCL (Tone P300) was measured with a Brookfield RVT viscometer having a No. 7 spindle at 20 and 50 rpm. The polymer was melted in a beaker and surrounded by a temperature controlled water bath, the temperature of which was measured

with an electronic thermometer sensitive to ±0.1° C. The viscosity was 51,200 cps at 60° C. PCL (Tone P700)) is solid at 60° C. The molecular weight of PCL (Tone P700) was determined by gel permeation chromatography and was found to be 100,000 (polystyrene equivalent in dichloromethane).

Table 2 sets out the properties of the coated sutures of Table 1.

The general texture and feel of a suture such as flexibility, smoothness and hardness was observed by handling the suture and drawing between fingers. Typical observations as set out in Table 2 are stiff, silky, waxy.

The slipdown property of a suture was determined by tieing tightly a two-throw square knot, then grasping the long ears and pulling apart. If the suture was drawn through the knot, giving the appearance of the knot slipping down the braid, it was marked as excellent (exc.), good, or acceptable (acc.) depending on the ease of slipdown. If the knot seized or was difficult to slip down, the suture was marked as locks, poor, or rachety, depending on the difficulty of slip down.

The slipdown property was also tested under wet conditions by immersion of the unknotted suture in water for 5 seconds and immediately testing thereafter.

The knot security of a suture was tested by tying firmly a triple throw square knot and pulling the suture from a patient's side until the knot slipped or the suture broke. If the knot slipped, knot security was marked poor. If the suture broke without slip, the knot was sufficient to hold the suture at the knot and was marked acceptable in Table 2.

The knot security was tested under wet conditions by immersion of the unknotted suture in water for 5 seconds and immediately testing thereafter.

The wet knot slipdown was tested by tieing tightly a two-throw granny knot and slipping down the knot. The knot was then wetted by rubbing with fingers dipped in water. An attempt was then made to slip the knot down further. If the knot slipped both dry and wet, the suture was marked as acceptable, good, or excellent depending on the ease of the slip. If the knot slipped dry but not wet, the suture was marked as locking. If the slip was poor wet and dry and locking was difficult to determine, the suture was marked poor, or rachety.

TABLE 2

Example	Texture	2 throw square slipdown		3 throw square slipdown		2 throw granny slipdown, wet knot	Comments
		dry	wet	dry	wet		
1	stiff	exc.	poor	acc.	acc.	locks	exc. dry, poor wet
2	powdery smooth	poor	locks	acc.	acc.	locks	poor lubr. overall
3	stiff	exc.	poor	acc.	acc.	locks	exc. dry, poor wet
4	silky	acc.	acc.	acc.	acc.	locks	acc. lubr. but locks
5	very stiff	poor	locks	acc.	acc.	locks	very poor lubr., locks
6	very stiff	locks	locks	acc.	acc.	locks	as 5
7	stiff, rough	rachety	locks	acc	acc.	poor	poor lubr. esp. wet
8	silky	exc.	poor, rachety	acc.	acc.	locks	exc. slipdown dry, but not when wet

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000073

TABLE 2-continued

Example	Texture	2 throw square slipdown dry	2 throw square slipdown wet	3 throw square slipdown dry	3 throw square slipdown wet	2 throw granny slip-down, wet knot	Comments
9	stiff, rough	exc.	exc.	acc.	acc.	exc., no locking	excellent
10	very rough	rach-ety	rachety	acc.	acc.	rachety	poor lubr., not affected by water
11	stiff, waxy	very good	good	acc.	acc.	rachety	fairly good, not much affected by water
12	stiff, smooth	rach-ety	rachety	acc.	acc.	rachety	poor lubr., not affected by water
13	rough	fine to rach-ety	good	acc.	acc.	acc.	rachety dry, good wet
14	waxy, rough	good	good	acc.	acc.	good	good, not affected by water
15	rough	poor	poor	acc.	acc.	poor	poor lubr. overall
16	stiff, waxy	exc.	exc.	acc.	acc.	exc.	as 14
17	stiff, waxy	exc.	exc.	acc.	acc.	exc.	as 14
18	silky, good feel	exc.	exc.	acc.	acc.	exc.	exc. good feel, good lubr., not affected by water
19	stiff	exc.	exc.	acc.	acc.	exc.	as 18.

"lubr.": lubricant

COMPARATIVE EXAMPLE 20

An uncoated suture of polyglycolic acid (54 inch long), size 3-0 was immersed in 100 ml of coating solution comprising 95.0 ml methylene chloride and 5.00 g of Tone polyester 0240 (formerly Niax Polyol D560) of Union Carbide Corporation. The manufacturer specifies a molecular weight of 2000 and a viscosity of 500 cps at 60° C. for Tone polyester 0240. The coating solution was obtained by dissolving the Tone polyester 0240 at room temperature in a 200 ml beaker in 3 minutes using a magnetic stirrer.

The suture was immersed in the coating solution for one minute and air-dried at room temperature. The % coating on the suture was 5.9.

Knot slip and knot security were determined as follows.

Knot	Result
2 throw square slip down	slips about 0.5 inch, locks and breaks
3 throw square slipdown	locks

-continued

Knot	Result
2 throw granny slipdown (dry)	acceptable slip
2 throw granny slipdown (wet)	acceptable slip

I claim:

1. A surgical suture comprising a braided multifilament of poly(glycolic acid or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer of said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity at 60° C. of at least about 50,000 centipoise or being solid.

2. A suture according to claim 1 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C_{10}–C_{30} fatty acids.

3. A suture according to claim 2 wherein said sterol is a mixture of cholesterol and lanosterol.

4. A suture according to claim 1 wherein said lubricating agent is present in an amount of 0.5 to 10% by weight based on the weight of the suture.

5. A needled surgical suture comprising at least one filament of poly(glycolic acid) or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer or said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity of 60° C. of at least about 50,000 centipoise.

6. A needled surgical suture according to claim 5 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C_{10}–C_{30} fatty acids.

7. A surgical suture package comprising a sterile enclosure containing a sterile needled surgical suture, the suture comprising at least one filament of poly(glycolicacid) or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer of said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity at 60° C. of at least about 50,000 centipoise or being solid.

8. A package according to claim 7 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C_{10}–C_{30} fatty acids.

* * * * *

United States Patent Office

3,527,650
Patented Sept. 8, 1970

1

3,527,650
SUTURE COATING OF POLYETHYLENE OR POLYTETRAFLUOROETHYLENE

Edward A. Block, Somerville, N.J., assignor to Ethicon, Inc., a corporation of New Jersey

No Drawing. Filed Dec. 21, 1967, Ser. No. 692,283
Int. Cl. A61l 17/00
U.S. Cl. 117—7 8 Claims

ABSTRACT OF THE DISCLOSURE

The hand and lubricity of a braided polyethylene terephthalate suture are improved by applying to the surface thereof polymers of polyethylene or polytetrafluoroethylene having a lower coefficient of friction than the suture and a styrene-acrylic ester copolymer resin binder therefor.

The present invention relates to nonabsorbable surgical sutures and more specifically to braided multifilament sutures of polyethylene terephthalate. Braided polyethylene terephthalate sutures have been used by many in the surgical profession for years and actually are preferred over silk by many surgeons for their strength and lack of tissue reactivity. Other surgeons prefer to use waxed silk when a nonabsorbable suture is required because of its excellent hand, ease of knotting, and ease of passage through tissue.

It is a known disadvantage of polyethylene terephthalate sutures that the knot may slip unless repeated knots are tied. Attempts have been made to improve the knotability of polyethylene terephthalate by modifying the surface thereof to decrease lubricity. One method of doing this is described in U.S. Pat. No. 3,307,971, which issued to Leonard D. Kurtz in March of 1967.

The present invention is directed to increasing the lubricity of a braided polyethylene terephthalate suture by applying a surface coating of a nontoxic and physiological inert resin that has a lower coefficient of friction than the polyethylene terephthalate, such as, polytetrafluoroethylene or polyethylene.

Polytetrafluoroethylene has been applied to braided polyethylene terephthalate sutures for the purpose of filling the interstices of the braided structure and achieving the characteristics of a solid monofilament. U.S. Pat. No. 3,322,125 described in Example I impregnating a braided 4/0 polyethylene terephthalate suture with a suspension of polytetrafluoroethylene particles having a particle size of about 0.2 micron. The suture is dried and stretched at 450° F. whereby the particles of polytetrafluoroethylene are trapped within the body of the suture.

The process described in U.S. Pat. No. 3,322,125, however, does not produce a satisfactory surface coating of polytetrafluoroethylene because the polytetrafluoroethylene particles do not adhere to the surface of the suture material. The particles can flake off and produce foreign body reactions near the suture site. It has now been discovered that polytetrafluoroethylene and other resinous particles having a coefficient of friction lower than that of the braided polyethylene terephthalate surface may be cemented to the surface of the braided polyethylene terephthalate suture with a binder resin which prevents flaking of the resinous particles.

Binder resins that are suitable for use in securing polytetrafluoroethylene and similar resinous particles having a lower coefficient of friction than polyethylene terephthalate to the surface of a braided polyethylene terephthalate suture are the non-ionic, self-cross linking, or cross-linkable acrylic polymers, such as Rhoplex HA–12 and Rhoplex B–15, manufactured by Rohm and Haas Company, Philadelphia, Pa., and thermoplastic acrylic

2

polymers, such as Hycar 2601, manufactured by B. F. Goodrich Chemical Company of Cleveland, Ohio and copolymers of an acrylic ester and styrene, such as Acrotex Resin 134, manufactured by the American Cyanamid Company, Bound Brook, N.J.

In the practice of the present invention, a braided polyethylene terephthalate suture is passed through an aqueous mixed dispersion of an acrylic latex of the type identified above and polytetrafluoroethylene particles or polyethylene particles. The ratio of acrylic latex to polytetrafluoroethylene particles in the dispersion is about 1:1 but may be increased to improve the adhesion of the lubricating particles to the surface of the suture or decreased to increase the lubricity of the surface coating. The dwell time of the braided suture with the polytetrafluoroethylene dispersion is just sufficient to coat the surface as penetration of the lubricant particles into the interstices of the suture is not necessary or desired. The braided polyethylene terephthalate after it leaves the coating bath is dried and heat cured. The structure of the braided polyethylene terephthalate suture is altered by the shrinkage that occurs during the curing process. To restore the original close braided structure and control the size (diameter), the coated, braided suture after cooling is heated and stretched under tension. The coated, braided strand may be conveniently heated by moving it one or more times past a steel plate maintained at a temperature between 350° F. and about 440° F. at the rate of 50 to 100 yards per minute. The smaller size sutures, e.g., size 6/0, may be stretched in this manner about 25 percent to 40 percent. The larger sutures, e.g., size 2, are stretched as much as 40 percent to 60 percent.

It is an important aspect of the present invention that the binder resin is flexible and bound to the braided suture in such a manner that it does not crack, flake, or come off of the suture during the heat-stretching step.

The product so obtained has an improved hand and surface lubricity. Yet the knot will not slip if a double square knot is tied. The surface lubricity of a coated polyethylene terephthalate suture may be demonstrated by the following test:

To the cross bar of an Insthon tester is secured a 3½" pulley and a 2" pulley. Using a B cell and the associated upper jaw (red), the instrument is calibrated with a 100 gram weight on the B cell clamp to full scale deflection on the ×1 scale.

To determine the surface lubricity of a coated strand, a 45" length of suture is clamped in the center of the upper jaw; the free end is passed counterclockwise around the 3½" diameter pulley, and a counterclockwise single throw is made approximately 1½" above the face of the 3½" diameter pulley wheel. The free end of the suture is then passed over the 2" diameter pulley wheel and secured to a 50 gram weight. The distance from the periphery of the pulley face to the bottom of the B cell clamp is 2½".

In operation, the ×10 scale on the Instron tester is used (1,000 grams full scale) and the crosshead speed and chart speed are 20" per minute.

As the suture passes over itself, a curve is plotted on the graph paper. Since a braided suture has braid protrusions and is somewhat elliptical in cross-section, a smooth curve does not appear. The "stick" portion of a stick-slip curve is produced when it is easier for the suture to stick to itself and elongate than to slip. As the suture is elongated more and more, the tension continues to build up until either the yield point of the suture is reached or until the cohesive force is overcome and the suture slips. This cycle is repeated producing a saw-tooth pattern on the chart.

The surface lubricity of the braided suture may be determined from the maximum and minimum friction

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000075

peaks on the graph in accordance with the following equation:

$$\text{average lubricity} = \text{minimum peak} + \frac{(\text{maximum peak} - \text{minimum peak})}{2}$$

The lubricity of the surface as determined by the test described above may be confirmed subjectivly (by feel).

Microscopic examination of the surface coated braided sutures confirms that the surface coating does not scuff or flake off on tie-down.

The invention will be understood from the following examples which illustrate preferred embodiments of the inventive idea.

EXAMPLE I

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0[1], passed beneath two nylon rollers immersed in a trough containing a polytetrafluoroethylene resin dispersed in a thermosetting acrylic latex (Emralon 312, manufactured by Achesin Collids Company, Port Huron, Mich.). The polytetrafluoroethylene resin constitutes about 50 percent of the total resin solids. The braided multifilament moves through the trough at the rate of about 16 yards per minute, the surface of the skein being in contact with the liquid dispersion for about 0.6 to 0.9 seconds. The concentration of resin solids in the trough was maintained at 50±5 percent throughout the run.

After coating, the skein is heated in an over for ½ hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 500 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE II

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it though one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 45 percent solids (Rhoplex HA-12)	707
Polytetrafluoroethylene resin 60 percent solids (Teflon 30 manufactured by E. I du Pont de Nemours and Company, Inc., Wilmington, Del.)	1,588
Water	7,705

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 35 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.8 percent of the total suture weight. The surface lubricity, as measured by the Instron surface lubricity test described above, is 550 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE III

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is passed beneath two nylon rollers immersed in a trough containing 340 parts of a polytetrafluoroethylene resin containing 60 percent resin solids and 151 parts of a thermosetting acrylic latex (45 percent solids). The acrylic latex is an interpolymer of 90 parts of 2-ethylhexyl acrylate, 12 parts glycidyl acrylate, 90 parts styrene, and 8 parts methacrylic acid. The braided multifilament moves through the trough at the rate of about 16 yards per minute, the surface of the skein being in contact with the liquid dispersion for about 0.6 to 0.9 second.

After coating, the skein was heated in an oven for ½ hour at 275° F. and heat stretched 45 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 2.6 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 530 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE IV

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 46 percent solids (Rhoplex B-15)	832
Polytetrafluoroethylene resin 60 percent solids (Teflon 30)	1,868
Water	7,300

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 50 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating. The surface lubricity, as measured by the Instron surface lubricity test described above, is 490 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE V

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is passed beneath two nylon rollers immersed in a trough containing 1,494 parts of a tetrafluoroethylene resin containing 60 percent resin solids (Teflon 30); 1,192 parts of a styrene acrylate copolymer resin latex (Aerotex Resin 134); and 7,314 parts of water. The braided multifilament moves through the trough at the rate of about 20 feet per minute.

After coating, the skein was heated in an oven for ½ hour at 300° F. and heat stretched 55 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.94 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 466 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE VI

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Polyethylene resin 50 percent solids Valsof K070 manufactured by Valchem Chemical Division of United Merchants and Manufacturers, Inc., New York, N.Y.	126
Acrylic resin (45 percent solids) (Rhoplex HA-12)	126
Water	748

[1] Diameter 10-13 mils as determined by the method described at p. 918 of the U.S. Pharmacopeia, vol. XVII.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000076

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.3 percent of the total suture weight. The dry straight tensile strength is 9.1 pounds, and the dry knot strength is 6.4 pounds. The coated suture does not slip when tied with a double square knot.

EXAMPLE VII

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Polyethylene resin 30 percent solids Valspex N-123 manufactured by the Valchem Division of United Merchants and Manufacturers, Inc., New York, N.Y.	3,375
Non-crosslinking acrylic resin (Hycar 2601)	675
Water	5,950

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 45 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.5 percent of the total suture weight.

EXAMPLE VIII

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 50 percent solids (Hycar 2601)	720
Polytetrafluoroethylene resin 60 percent solids (Teflon 30)	1,868
Water	7,412

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating. The surface lubricity, as measured by the Instron surface lubricity test described above, is 553 grams. The coated suture does not slip when tied with a double square knot.

The invention described and illustrated herein before and secured by this Letters Patent is defined in the following patent claims.

What is claimed is:

1. A braided polyethylene terephthalate suture having a surface coating of a first resin selected from the group consisting of tetrafluoroethylene and polyethylene and a second binder resin comprising a styrene-acrylic ester copolymer, the weight ratio of said first resin to said second resin being between about 1:1 and about 3:1.

2. The suture of claim 1, wherein said first resin is polytetrafluoroethylene.

3. The suture of claim 1 wherein said acrylic ester copolymer is a copolymer of 2-ethylhexyl acrylate.

4. The suture of claim 1, wherein said first resin is polyethylene.

5. A method of improving the hand and surface lubricity of a braided polyethylene terephthalate suture comprising the steps of immersing the suture in an aqueous dispersion of a first resin selected from the group consisting of tetrafluoroethylene and polyethylene and a second binder resin comprising a styrene-acrylic ester copolymer, the weight ratio of said first resin to said second resin being between about 1:1 and about 3:1, for a time sufficient to wet the surface of said suture but not sufficient for said resins to substantially penetrate into the interstices of said suture, drying the suture, curing the binder resin, and heating and stretching the suture at an elevated temperature, whereby a resinous coating is formed on the surface of the suture.

6. The method of claim 5, wherein said first resin is polytetrafluoroethylene.

7. The method of claim 5, wherein said suture is heated at about 300° F. for about one-half hour.

8. The method of claim 5, wherein said first resin is polyethylene.

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ALFRED L. LEAVITT, Primary Examiner

A. GRIMALDI, Assistant Examiner

U.S. Cl. X.R.

117—138.8, 139.5, 161; 128—335.5

HERMES DECLARATION
EXHIBIT 15 – PART 3 OF 8

United States Patent [19]

Kurtz

[11] **Patent Number:** **4,470,941**

[45] **Date of Patent:** **Sep. 11, 1984**

[54] **PREPARATION OF COMPOSITE SURGICAL SUTURES**

[75] Inventor: Leonard D. Kurtz, Woodmere, N.Y.

[73] Assignee: BioResearch Inc., Farmingdale, N.Y.

[21] Appl. No.: 384,245

[22] Filed: Jun. 2, 1982

[51] Int. Cl.[3] B29B 3/02

[52] U.S. Cl. 264/136; 128/335.5; 264/108; 264/134; 264/171; 264/174; 264/288.8; 264/290.5; 264/345

[58] Field of Search .... 428/397, 375, 372; 425/113, 192 R; 264/174, 562, 108, 288.8, 134–137, 345, 210.8, 290.5, 171, 210.7; 128/335.5

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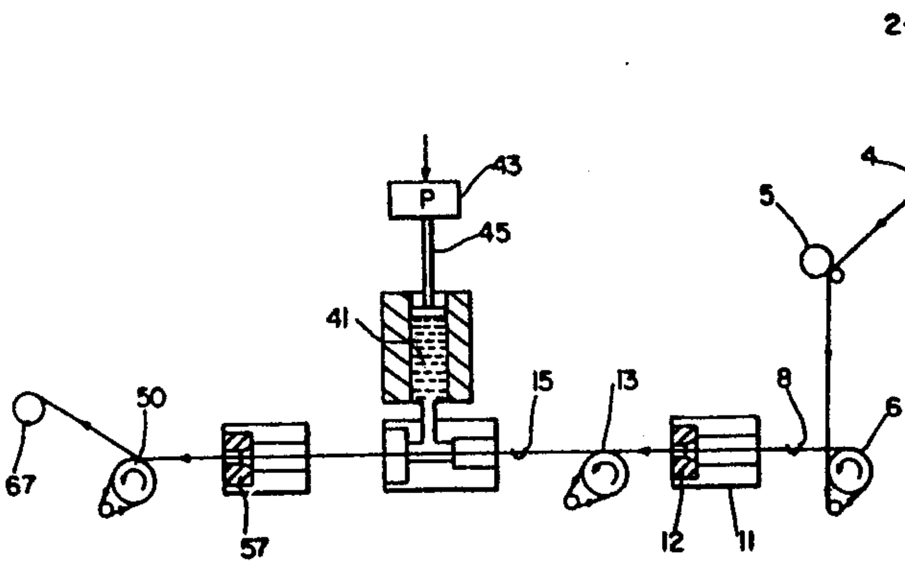
Primary Examiner—Jeffery Thurlow
Attorney, Agent, or Firm—Larson and Taylor

[57] **ABSTRACT**

Composite sutures of dissimilar synthetic polymer materials are prepared by forming a thread comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising a second synthetic polymer in intimate association with and present uniformly along the length of said first synthetic polymer, softening the second synthetic polymer to cause it to flow, applying pressure to the softened polymer to redistribute it throughout the plurality of fibers, and into the interstices thereof and sterilizing the thread to form a suture thereof.

33 Claims, 2 Drawing Figures



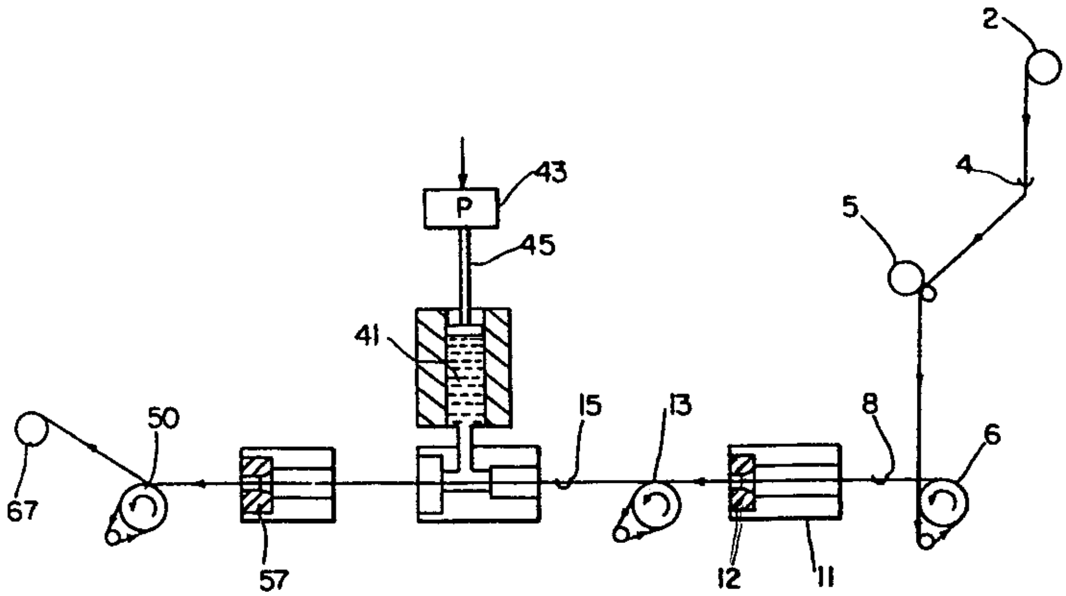

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FIG. 1

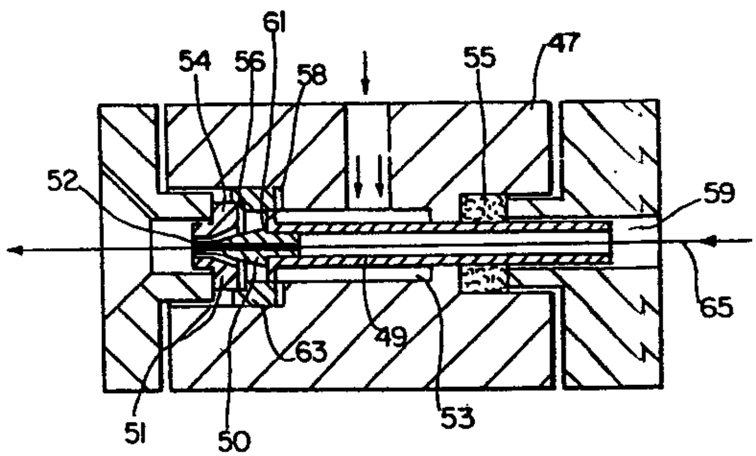
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FIG. 2

PREPARATION OF COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a method for preparing composite surgical sutures. More particularly, the invention is directed to methods by which composite sutures of improved lateral strength are obtained.

2. Brief Description of the Prior Art

Composite sutures offer a number of advantages recognized by the prior art. For instance, there are many synthetic fibers which per se are unsuitable for use in sutures because they lack one or more of the properties required in surgical sutures but which possess, nevertheless, certain other properties considered desirable in sutures. By way of example, fibers drawn from many synthetic polymers are too stiff and do not satisfy the knottability requirements of sutures. At the same time these synthetic polymers may possess a tensile strength that renders their use in sutures highly desirable. It is not surprising, therefore, that there have been numerous attempts to combine the best properties of different synthetic materials by compositing them in various ways. These compositing attempts have not been without shortcomings, however.

The principal difficulties involved in the preparation of composite sutures have resided in the fact that polymers whose properties render them desirable for compositing often lack cohesiveness for one another and are otherwise unable to adhere to each other. Many have attempted to remedy these problems by resorting to chemical adhesion through reactive groups provided the polymer components and/or chemical additives to assist in the binding of one polymer component to the other. These techniques, in addition to being costly have in large part proved unsuccessful.

Other attempts to integrate multi-components strands in the production of strings for athletic rackets has been described, for example, in U.S. Pat. No. 4,275,117 to Steven J. Crandall and involves subjecting a fibrous strand composed of fibrous materials having differing melting points to heating conditions sufficient to melt some but not all of the fibrous materials. While perhaps satisfactory for tennis string production or the like, this method of forming composites, as in the case of other aforementioned prior art methods, provides unsatisfactory surgical sutures in that they are found to possess poor lateral strength manifested by a lack of stability against abrasion, kinking and fibrillation during knotting.

Accordingly, it is an object of the present invention to provide a method whereby composite sutures of synthetic polymers having improved lateral strength, that is, composite sutures stabilized against abrasion, kinking and/or fibrillation during knotting are obtained.

Yet another object of the invention is to provide a method of enabling preparation of composite sutures whose surface characteristics, tensile strength and/or knot strength can be tailored to desired specifications.

A further object of the invention is to provide a method of preparing a composite suture whereby one synthetic polymer is tenaciously anchored to the other without the use of chemical adhesion, chemically reactive groups or additives to bind one polymer to the other.

A still further object of the invention is to provide a method for composite suture preparation which enables the use of synthetic fibers heretofore unsuitable for use in suture manufacture.

Another subject of the invention is to provide a method of manufacturing a composite suture having monofilament characteristics which is free of flaking on its outer surface and which retains in large part the flexibility, knottability, knot retention and tensile strength that characterizes multifilament sutures.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by forming a thread having interstices therein, comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising a second synthetic polymer in intimate association with and present along the length of at least one of said plurality of fibers, softening said second synthetic polymer to cause flow thereof, applying sufficient pressure to the softened polymer for a time sufficient to redistribute it throughout the plurality of fibers of said first synthetic polymer and into the interstices thereof.

Absolutely essential to the construction of the composite sutures is the pressure step of the method for without it composite sutures having acceptable lateral strength are not obtained. The pressure can be applied to the softened polymer component of the thread in any suitable way with the only proviso being that sufficient pressure be used for a time sufficient to redistribute the softened polymer throughout the fibers of the first synthetic polymer and substantially fill the voids in the thread. According to one preferred embodiment of the invention the pressure is applied by placing the thread under tension during the softening operation. Another preferred method by which the pressure can be applied in the method of the invention is to pass the thread immediately after the softening operation through a compression die having a reduced diameter relative to that of the diameter of the thread so that the necessary pressure can be applied. Although unnecessary, it is preferred in the latter case to use a compression die heated to above the melting point of the polymer component softened. If desired, both forms of pressure application can be utilized as by first effecting the pressure by placing the thread under tension followed by passing the thread through the compression die of reduced diameter.

Since the thread is under pressure, the softened dissimilar polymer exudes into and through interstices existing in the plurality of unsoftened fibers, substantially filling same and forming an internal cast within the matrix of unsoftened fibers upon resolidification. The internal cast of the softened polymer may be continuous or discontinuous and will appear in cross-section in the composite suture as a homogeneous, solid phase throughout the plurality of unsoftened fibers. In most instances, it will be preferred to use an amount of softened polymer sufficient to form upon redistribution throughout the plurality of fibers of the unsoftened synthetic fiber an external cast extending continuously throughout the thread.

Also, where enough of the polymer component softened is present, the liquified polymer exudes through the interstices of the unsoftened fibers and onto the surface of the thread so as to form a coating thereon.

In all instances, however, the internal cast formed within the matrix of unsoftened fibers serves as a tena-

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000080

cious "anchor" onto which additional softened synthetic polymer can be secured as by coating, if desired.

Composite sutures prepared by the present invention having coatings of the exuded synthetic polymer component are preferably smoothed, for instance, by passing them through a heated smoothing die. The smoothed composite thread may then be sterilized if desired to form a surgical suture. In many instances, it may be necessary to further coat the smoothed composite with additional similar synthetic polymer as by extrusion or melt coating to seal and further strengthen the composite thread formed. In addition where the thread is in braided form, subsequent coating tends to eliminate any undulating effect that results as a consequence of the braid and provide a flexible, composite polyfilamentous composite suture having a monofilament-like structure exhibiting improved knottability and knot retention. The improvement in knottability and knot retention characteristics is obtained by virtue of the fact that when a knot is "thrown" and tied down, the suture undergoes a marked deformation in the knot due to the "hills and dales" of the underlying thread.

DETAILED DESCRIPTION OF THE INVENTION

By the term "softening" as used herein and the appended claims is meant any operation by which one of the synthetic polymer components of the thread treated but not the other is brought from a solid or highly viscous state to a viscosity causing flow of the synthetic polymer under the prevailing conditions. This "softening" can be achieved by a variety of ways such as by the use of heat, selective solvents, high energy sources such as lasers, etc. Other suitable ways of effecting the softening will readily come to the mind of those of ordinary skill in this art.

In the aspect of the invention wherein the softening is induced by heating, the thread, comprised of a matrix of a plurality of fibers of a first synthetic polymer and a second solid, dissimilar synthetic polymer having a melting point lower than the melting point of said first synthetic polymer is heated at a elevated temperature sufficient to melt and liquify the dissimilar synthetic polymer, to a viscosity permitting flow throughout the matrix.

Similarly, where the "softening" is induced by a solvent, the thread of dissimilar synthetic polymer components is contacted at a temperature and with a solvent capable of solubilizing or softening the second synthetic polymer but not the first at the contact temperature. The contact time will vary depending principally upon the particular synthetic polymer to be softened and the solvent and contact temperature employed. In all instances, however, the contact time will be sufficient to cause one of the synthetic polymer components to flow, that is, to reduce the viscosity of the polymer to where it flows under the external pressure applied according to the invention and through the remaining, or unsoftened synthetic fibers so as to fill the voids or interstices therein. There is thus formed an internal cast throughout the thread which is dried to resolidify the exuded softened polymer component.

The thread softened in accordance with the present invention can assume a variety of structures and the polymer component to be softened can be present during the softening in any desired form such as a film or fiber, or as a coating on the polymer not softened. In one embodiment, for example, the thread is comprised of lower melting point synthetic polymer fibers in a plied, twisted, braided or commingled construction with synthetic polymer fibers of higher melting point. A preferred form of this embodiment involves heating under tension a thread comprised of a cover of a polyfilamentous synthetic polymer surrounding a core of at least one but preferably a plurality of fibers of a dissimilar synthetic polymer having a lower melting point than the synthetic polymer of said cover.

Alternatively, the thread to be heated pursuant to the present invention can comprise, at least in part, a plurality of synthetic polymer fibers coated with a dissimilar synthetic polymer having a melting point lower than that of the synthetic polymer fiber substrate, which coated fibers are in a plied, twisted, braided, commingled or simply aligned construction.

The proportions of lower melting point synthetic polymer component to higher melting point synthetic polymer component employed in the thread heated in accordance with the invention will vary depending principally upon the particular components selected, whether or not a continuous or discontinuous internal cast is desired and whether or not a composite coated with melted components is the intended product. In all instances, however, the component melted should be present in amounts at least sufficient to provide adequate anchoring sites for additional like synthetic polymer material that may be subsequently applied as a coating to the composite thread formed.

In general, the ratio of higher melting point synthetic polymer material to lower melting point synthetic polymer material in the initial thread required to achieve adequate anchoring sites is at least 0.5:1 on a volume bases. Ratios of melted to unmelted synthetic polymers in excess of 1:10 up to 2:1 are generally required, however, if it is desired to not only fill all the interstices of the thread but to coat the thread as well. Proportions in excess of about 12:1, can create processing difficulties due to thread line non-uniformities.

Heating of the precursor thread of multiple synthetic polymer components to temperatures above the melting point of one of the synthetic components can be conducted in any suitable manner as by passing it through a suitable oven preferably under an inert gas such as nitrogen. As the composite thread passes through the oven, the synthetic component of lower melting point melts and under the applied pressure exudes through the voids present in the plurality of higher melting fibers remaining leaving them substantially filled. Preferably the softened polymer exudes onto the surface under the tension applied.

Any excess melted synthetic polymer can then be trimmed off manually but it is preferred that the thread structure thus formed be passed through a heated die which trims nubs from the thread and otherwise smooths the external surface of the thread. If the thread thus formed is to be coated, it is important to select a die in this operation which provides a precoated yarn that is at least 20–40 microns thinner than the suture class limits in order to leave room for the coating. Again, it is preferred that this operation be conducted under an inert gas such as nitrogen. Stretch may also be applied during the smoothing operation. The thread may be passed through the heating oven and/or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface polymer be removed, but some of it should be used to fill the ups and

downs of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the polymer remaining on the surface follows the contours of the thread and any subsequently applied polymer coating will follow these contours.

The temperature employed in the heating oven will vary depending on the polymer components and the speed at which the thread is passed through the oven. As aforementioned, the temperatures should be raised above the melting point of the polymer of lower melting point to a level at which the polymer melts and reaches a viscosity permitting it to exude through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which then the lower melting polymer to a point where it runs off should be avoided as they tend to exude too much polymer and fail to product a solid cast structure.

Regardless of the method utilized to introduce the required pressure, the actual or optimum pressure applied will vary depending principally upon the particular synthetic polymer components that make up the thread, the softening conditions, the flow viscosity of the softened polymer compound and the nature of the thread construction, i.e. braid, twist, yarn, etc. It is important to note, however, that giving the thread a high level of stretch during the heating operation reduces or eliminates the necessity of applying stretch in any subsequent coating and final sizing stages that may be employed.

The optimum heating temperature employed in a softening operation wherein one of the polymer components is melted will not only depend upon the particular polymer of lower melting point employed but also on the melting point and/or the zero strength temperature of the higher melting polymeric component forming the matrix. In the case of polymers having high crystallinity, the more important consideration is not so much the melting point of the lower melting polymer but rather the temperature at which the polymer reaches a fluidity or viscosity that facilitates exudation. In the case of non-crystalline polymers, on the other hand, only the last criterion applies since non-crystalline polymers do not have a melting point. Usually this temperature is in excess of the melting point of the polymer. For example, to obtain acceptable fluidity with isotactic polypropylene which melts at about 160° C., the polymer should be heated at a temperature within the range of about 180° to 280° C. depending on its molecular weight. Fiber-forming polyethylenes will generally process in the range of about 160° to 275° C. Nylon 66 (polyhexamethylene adipamate) usually will require a heating temperature of about 280° to 295° C. and polyethylene terephthalate a heating temperature of about 270° to 320° C.

Smoothing die temperatures will also be above the melting point of the lower melting synthetic polymer and usually below the melting point of the dissimilar synthetic polymer component. In most instances, the smoothing die temperatures will conform closely to the temperature employed in the heating, i.e. structure formation/precoating stage. Preferably the smoothing die temperature about 5 to 15 degrees below that used in the structure formation/precoating stage.

In a preferred embodiment of the invention, the smooth composite suture structure formed is subjected to coating stage wherein polymer is melt extruded onto the structure. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth composite suture structure is simply fed through the extrusion coating die and coated with additional polymer of the same type as used in the structure formation, i.e. precoating stage. Optionally, a smoothing operation can follow this stage using a heated die as described above.

The extrusion temperatures employed in the coating stage depend upon the polymer added and generally will conform to those employed in the heating operation. It has also been found that when the coating is done with apparatus of the melt flow rheometer type the higher the coating temperature, other conditions being equal the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperatures which results in increased polymer flow under a given applied force. The thickness of the polymer coating can be easily regulated by changing the applied extrusion force. If the coated suture is to be subjected to a final sizing operation this thickness should be 30-40 microns larger than the required final size.

After a coating stage, the coated thread preferably undergoes a final size stage. Ordinarily, a thread leaving the coating stage is thicker than the USP size limits. In order to bring it to USP size requirements, a size or calibration process is carried out. The final sizing in such cases is made by passing the coated suture through the calibration die, preferably a non-split die. In addition to its sizing function the calibration die has additional operations: (a) all possible homogeneities in the coating are eliminated (b) squeezing the coated suture through the hot calibration die results in additional co-melting of the polymer in the sheath with the polymer on the surface of the precoated thread, thus improving the adhesion of the coating to the thread and (c) if for some reason the flow rate of the polymer melt changes at extrusion during the coating stage, it results in increased thickness of the coating. The calibration die will control the final thickness by scraping off excess polymer coating.

The coated suture should contact the walls of the calibration die while still in the molten state, in order to prevent abrasion of cold polymer coating passing through the calibration die. The distance between the outlet of the coating die and the calibration die should be minimal in order to secure a coated suture which is sufficiently rigidified so that when it goes through the calibration die it takes the shape of the die but at the same time it should be soft enough to give a smooth finish. Distances of 5 to 7 cm have been found suitable. On leaving the coating die the coating thickness of the suture should be significantly larger (by 30-40 m) than the inner diameter of the calibration die in order that the space in the capillary part of the die and the entrance to the die will always be filled by the polymer melt. On the other hand, too heavy a coating will cool faster leaving the coating die and will not be heated up rapidly enough to pass through the calibration die. This will disturb the scraping action and will produce breaks in the suture or a rough surface.

When softening of the second synthetic is effected by the use of solvent, the solvent selected will depend, of course, upon the nature of the first component of thread treated since the latter must not soften during the operation. The following are illustrative of solvents generally suitable for use in softening exemplary types of synthetic polymers:

Polyesters—mixtures of halogenated hydrocarbons (e.g. methylene chloride) and halogenated alkanols (e.g. hexafluoroisopropanol).

Aromatic polyamides—strong acids and bases

Nylons—phenols

Polyolefins—aromatic hydrocarbons (e.g. xylene, toluene)

The synthetic/polymer components selected for compositing in accordance with the present invention are without limitation provided they are toxicologically acceptable, fiber- or film-forming polymers, possessing softening points sufficiently distant from each other to permit softening of one without softening or otherwise degrading the other. Thus, the synthetic polymers can be thermoplastic or non-thermoplastic polymer materials illustrative of which are homopolymers and copolymers of a olefins of 1–6 carbons, e.g. polyethylene, polypropylene, polybutene, polyisobutylene, copolymers of ethylene and propylene and the like; polyacrylates such as polymethacrylate, polyethacrylate, and the like; polyamides such as Nylon 66, i.e. poly(hexamethylene adipamide), Nylon 610, i.e. (polyhexmethylene sebacamide), Nylon 6, i.e. polycaprolactam; aromatic polyamides, such as those described in U.S. Pat. Nos. 3,063,966; 3,600,350; 3,671,542 and 3,819,587, all incorporated herein by reference, particularly poly(p-benzamide); poly(p-phenylene terephathalamide); poly(2-chloro-p-phenylene terephthalamide; poly(2,6,-dichloro-p-phenylene-2, 6-naphthalamide; poly(p-phenylene-p,p-biphenyldicarboxamide; poly(p, p'-phenylene benzamide and poly(1,5-naphthylene terephthalamide); copoly(p,p'-diaminobenzanilide terephthalamide; polyesters of difunctional carboxylic acids and diols such as polyethylene terephthalate, poly(1,4-cyclohexylene dimethylene terephthalate); polystyrene; poly(acrylonitrile); polyurethane, polyethers, polyvinyls, polypeptides such as polylactides, polyglycolides and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Pat. Nos. 3,636,952 and 2,683,136, incorporated by reference herein; and pclymers of p-aminobenzoic acid.

Illustrative of suitable composite threads for treatment in accordance with the present invention are set forth in the following Table I:

TABLE I

Composite	Matrix	Extruding Polymer
1	polyethylene terephthalate	isotactic polypropylene
2	Kevlar(1)	polypropylene
3	Kevlar(1)	polyethylene
4	Kevlar(1)	polyethylene terephthalate
5	chain extended polyethylene(2)	atatic polypropylene
6	Kevlar(1)	polyglycolic acid
7	Nylon 66	isotactic polypropylene
8	Nylon 66	polyisobutylene
9	polyethylene terephthalate	Nylon 11

(1)aromatic polyamide product of DuPont Corporation
(2)high strength polyolefin yarn having straight pull tenacity of approximately 25–30 g/denier described in Keller A. and Barham, P. J., "High Modulus Fibres", Plastics and Rubber International, Feb. Vol. 6, No. 1 (1981) incorporated herein by reference.

The following examples are included to further illustrate preparation of composite sutures of the invention. In the examples, reference is made to the following brief description of the drawings wherein:

FIG. 1 is a schematic drawing of an apparatus useful in the three stage melting method of the present invention and

FIG. 2 is a schematic drawing in section of a spinneret useful in the extrusion coating of the formed composite suture employed in the apparatus of FIG. 1.

EXAMPLE I

Structure Formation or Precoating Stage

Directing attention to the drawings, using a conventional New England Butt braider machine polyethylene terephthalate (PET) strands of 40 denier are braided around a single core of 265 denier isotactic polypropylene to form a 4/0 raw or precursor thread with 4 ends of 40 denier PET in the cover and 1 end of 165 denier polypropylene in the core. The raw braid, wound around a reel 2, is fed through a guide 4, between nip rollers 5 about a feed roll (Godet) 6, through guide 8 into a heated 10 cm long tubular over inside Spinneret I designated 11 in FIG. 1. The lumen of Spinneret I without polyolefin feed serves this purpose, Heated Zone I in FIG. 1. A roll (Godet) 13 pulls the raw braid through the oven at a stretch ratio (SR) of 1.24. The heating oven is maintained at a temperature of 230° C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Spinneret I, large quantities of excess polypropylene which has melted out and formed nubs on the surface is trimmed off by a smoothing die 12 having an internal diameter (ID) of 0.180 mounted at the outlet of Spinneret I. The braid then continues through a Guide 15 to Spinneret II designated 39 which is an extrusion coating die apparatus shown in detail in FIG. 2.

Coating Stage

The smoothed precoated braid is pulled through Spinneret II by a roll (Godet) 50. Tension is let down on roll 50 so that some overfeed, i.e. a stretch ratio (SR) of approximately 0.9 is applied. Isotactic polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260° C. and the melt is forced by means of extruding weights 43 applying a force of 0.233 kg to a piston 45 into and through the tubing-type extrusion coating die apparatus 39.

Directing particular attention to FIG. 2, the extruding coating apparatus 39 is comprised of a holder indicated generally as 47 which houses a hollow guide tube 49 and a die holder 50 which retains a die 51. Die 51 has an outlet 52. The guide tube 49 is essentially positioned within the holder 47 so as to provide an annular chamber 53. A Teflon gasket 55 seals one end of the guide tube 49 within the holder while the other end is connected to die 51 and sealed by aluminum gaskets 54, 56 and 58. The guide tube contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the die 51 is positioned a hollow needle 63. The polypropylene melt from heated reservoir 41 is forced by piston 45 through channel 65, into annular chamber 53 and over needle 63. The impregnated/precoated thread 65 passes consecutively through guide tube 49, hollow needle 59, outlet 52 and is coated with the melt as it emerges from the due 51. The coating die is maintained at a coating temperature of 230° C.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

Final Sizing or Calibration Stage

The coated thread is passed to a Spinneret III designated 66 whose design is like that of Spinneret I except that a calibration die 67 (see FIG. 1) having an internal diameter of 0.220 mm is employed so as to provide a finished 4/0 suture. Spinneret III is positioned approximately 5 cm from the outlet of Spinneret II so as to provide a coated thread cooled to a rigidity that allows the coated thread when it enters Spinneret III to take the shape of calibration die 67 but is soft enough to give a smooth finish. The working temperature of Spinneret III is 220° C. Some overfeed (Stretch Ratio, SR approximately 0.9) is applied in the finishing stage as in the coating stage so as to improve the smoothness of the final product.

The finished suture is finally wound around receiving reel 69 and identified in the Table II below as CK suture 4-0.

Sutures of 3-0, 5-0 and 6-0 diameter size were similarly prepared and the mechanical properties of these sutures, identified below as CK sutures 3-0, 5-0 and 6-0 as well CK Suture 4-0 are reported in Table II. Also included for purposes of comparison are the mechanical properties of commercial sutures of like size.

knot values 50-60% higher than CK Sutures of the same size. For PET Braid Suture 4-0 and 5-0 the difference is about 20%.

Gurley Stiffness

By comparing all materials having the same 3-0 size (samples 1-5, all of them monofilaments) it is seen that the CK Suture 3-0 has the lowest Gurley Stiffness (G.S.). Size 3-0 polypropylene monofilaments (Prolene from ethicon and PP from Thiokol) and nylon monofilament (from Deknatel) have G.S. 2.5-3 times higher than that of similarly sized CK Suture. PET 3-0 monofilament has the highest G.S. —6.3 times higher than that of the CK Suture.

When comparing G.S. of size 4-0 materials (samples 6-10) it can be seen that the G.S. of Prolene 4-0 is still remarkably higher (by 68%) than that of the KC Suture but, on the other hand, the G.S. of PET 4-0 multifilament suture from Deknatel is two times lower than that of CK Suture 4-0. Such a result is not surprising when comparing the stiffness of multifilament with monofilament yarns.

In the size 5-0 the G.S. of CK Suture is 39% lower than that of Prolene, but 3.9 times higher than that of PET 5-0 multifilament.

TABLE II

No.	Type of Suture	Knot-pull Tensile Strength, F_{knot} (g) Required by USP*	Knot-pull Tensile Strength, F_{knot} (g) Measured	Percent Elongation (%)	Knot Security K_{av}	Knot Security $n_{knot}-1/5$	Gurley Stiffness G.S. (mg)
1	CK Suture 3-0	1200	1456	15.0	2	—	8.2
2	Prolene 3-0 (from Ethicon)	"	1504	58.3	3	$n_2/5 = 5$	19.8
3	PP Yellow Monofil. 3-0 (from Thiokol)	"	1430	39.4	3	$n_2/5 = 5$	24.9
4	Nylon White Monofil. 3-0 (from Deknatel)	"	1434	50.4	4	$n_3/5 = 5$	22.8
5	PET Monofil. 3-0	"	2430	76.1	3	$n_2/5 = 5$	52.0
6	CK Suture 4-0	750	930	12.8	2	—	5.9
7	Prolene 4-0 (from Ethicon)	"	946	56.7	3	$n_2/5 = 5$	9.9
8	PP Blue Monofil. 4-0	"	841	29.1	3	$n_2/5 = 5$	14.4
9	Nylon White Monofil. 4-0 (from Deknatel)	"	950	47.8	4	$n_3/5 = 5$	12.6
10	PET Green Braid Suture 4-0	"	1146	16.5	4	$n_3/5 = 1$	3.0
11	CK Suture 5-0	500	649	14.2	2	—	2.2
12	Prolene 5-0 (from Ethicon)	"	646	44.9	3	$n_2/5 = 5$	3.1
13	PP Blue Monofil. 5-0	"	532	31.5	3	$n_2/5 = 3$	5.9
14	Nylon White Monofil. 5-0 (from Deknatel)	"	577	51.0	4	$n_3/5 = 5$	5.4
15	PET Green Braid Suture 5-0 (from Deknatel)	"	770	25.2	4	$n_3/5 = 1$	0.6
16	Suture 6-0	250	318	11.0	2	—	0.4
17	Prolene 6-0 (from Ethicon)	"	270	50.0	3	$n_2/5 = 4$	0.6
18	PP Blue Monofil. 6-0	"	192	29.9	3	$n_2/5 = 5$	1.1
19	PET Monofil. 6-0	"	485	37.0	3	$n_2/5 = 5$	3.3

*The limits on F_{knot} apply to non-sterile sutures.

RESULTS

Knot-Pull Tensile Strength

Sizes 3-0, 4-0 and 5-0 CK Sutures have the same F knot as Prolene and Nylon Monofilaments (the differences being within the limits of 3% except for Nylon 5-0 which is 12% weaker than CK Suture 5-0). It should be noted that the values of 5-0 sutures are 20-30% higher than required by U.S.P. In size 6-0 the F knot of the CK Suture is 18% higher than that of Prolene. PP monofilament (blue) is remarkably weaker than the CK Suture (the difference increases from 11% in size 4-0 up to 66% in size 6-0).

PET sutures have F knot values higher than CK Sutures. PET Monofilaments of 3-0 and 6-0 have F

It may be safely stated that, when comparing CK Suture with other sutures of the same size, the G.S. of CK Sutures is remarkably lower than that of Prolene, PP, PET and Nylon monofilaments. This difference is particularly high when comparing with PET monofilaments of the same size. On the other hand, the G.S. of CK Sutures is remarkably higher than that of PET multifilament sutures. This results from the structure of CK Sutures.

Elongation

The P.E. of CK Sutures of all sizes varies from 11% to 15%. The P.E. of other monifilament sutures is much higher, for example: P.E. of Prolene in all sizes varies

from 45% to 58%; of PP monofilament from 29% to 39%; of Nylon monofilament from 41% to 51%; and of PET monofilament from 37% to 76%. Only P.E. of PET multifilament suture 4-0 (16.5%) is close to the desired value.

Knottability

Knottability results show that the CK Suture has the lowest stiffness and elongation when compared with other monofilament sutures. It can, therefore, be stated on the basis of these two quantitative parameters, that the knottability of the CK Suture is better than that of any other monofilament suture.

Knot Security

It may be seen from the Tables that all investigated materials can be divided into 3 groups with corresponding k_{sec}=2;3 and 4. CK Sutures belong to the group with k_{sec}=2. All Prolene sutures, PP monofilaments and PET monofilaments belong to the second group with k_{sec}=3. PET braids and nylon monofilaments belong to the third group with k_{sec}=4. It means that with CK Sutures, a secure knot can be tied using only two throws Square Knot. All other investigated materials need at least one additional throw for secure knot formation and nylon monofilaments and PET braids need even two additional throws.

Microscopic examination (250×) of a cross-section of the finished suture shows virtually no dead spaces present. The finished suture is free of stripping and cracking and possesses the smoothness of a monofilament.

In commercial production, needles may be attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time without a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

EXAMPLES II-IX

Example I is repeated using the following synthetic materials as the matrix and core, i.e. lower melting point component and conducting the heating in Heating Zones I and II as indicated.

Example	Matrix	Core	Spinneret I, °C.	Spinnerette II & III, °C.
II	Kevlar(1)	isotactic polypropylene	220	220
III	Kevlar(1)	polyethylene	225	220
IV	Kevlar(1)	polyethylene terephthalate	265	265
V	chain extended polyethylene(2)	atactic polypropylene	70	65
VI	Kevlar(1)	polyglycolic acid	238	230

-continued

Example	Matrix	Core	Heating Zone I, °C.	Heating Zone II, °C
VII	Nylon 66	isotactic polypropylene	230	222
VIII	Nylon 66	polyisobutylene	200	190
IX	polyethylene terephthalate	Nylon 11	237	237

(1), (2) See Table I, supra

It is claimed:

1. A method of preparing a surgical suture comprising forming a thread having interstices therein, comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising second synthetic polymer in intimate association with and present along the length of at least one of said plurality of fibers, said second synthetic polymer having a lower melting point than said first synthetic polymer, heating the thread to a temperature sufficient to liquify the second synthetic polymer but not the first synthetic polymer to cause flow thereof, placing the thread under tension during said melting to compress the thread and redistribute the liquified second polymer throughout the plurality of fibers of said first synthetic polymer so as to substantially fill the interstices of said thread, said liquified polymer being present during said redistribution in an amount sufficient to exude through the interstices of the unmelted fibers and onto the surface of the thread to form a coating thereon and to form an internal cast extending throughout said thread, said internal cast forming an anchor onto which additional second synthetic polymer can be secured, if desired, and sterilizing the resulting thread to form a surgical suture.

2. A method according to claim 1 wherein the second synthetic polymer is in fiber form.

3. A method according to claim 1 wherein the first synthetic polymer is aromatic polyamide.

4. A method according to claim 3 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

5. A method according to claim 3 wherein the aromatic polyamide is poly(1,4-benzamide).

6. A method according to claim 1 wherein the first synthetic polymer is chain extended, polyethylene having a straight pull tenacity of about 30 to 50 grams/-denier.

7. A method according to claim 3 wherein the first synthetic polymer is polyester.

8. A method according to claim 7 wherein the polyester is polyethylene terephthalate.

9. A method according to claim 1 wherein the second synthetic polymer is polyolefin.

10. A method according to claim 9 wherein the polyolefin is polyethylene.

11. A method according to claim 9 wherein the polyolefin is polypropylene.

12. A method according to claim 1 wherein said coating is subjected to smoothing.

13. A method according to claim 12 wherein said smoothing is effected by passing the composite after said heating through a heated smoothing die.

14. A method according to claim 1 wherein the composite formed is coated with the same synthetic polymer as said second synthetic polymer.

15. A method according to claim 14 wherein the coated composite is subjected to smoothing.

16. A method according to claim 15 wherein said smoothing is effected by passing the composite after said heating through a heated smoothing die.

17. A method according to claim 1 wherein the second synthetic polymer comprises at least one fiber.

18. A method according to claim 17 wherein the second synthetic polymer is polyolefin.

19. A method according to claim 18 wherein the polyolefin is polypropylene.

20. A method according to claim 19 wherein the polyolefin is polypropylene.

21. A method according to claim 1 wherein the first synthetic polymer is a polyamide terephthalate.

22. A method according to claim 21 wherein the polyamide is aromatic polyamide.

23. A method according to claim 22 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

24. A method according to claim 22 wherein the aromatic polyamide is poly(1,4-benzamide).

25. A method according to claim 21 wherein the polyamide is poly(hexamethylene adipamide).

26. A method according to claim 21 wherein the polyamide is polycaprolactam.

27. A method according to claim 21 wherein the polyamide is poly(hexamethylene sebacamide).

28. A method according to claim 20 wherein the polyamide is poly(w-aminoundecanoic acid).

29. A method according to claim 1 wherein the first synthetic polymer is polyester.

30. A method according to claim 29 wherein the polyester is polyethylene terephthalate.

31. A method according to claim 1 wherein the first synthetic polymer is extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

32. A method according to claim 1 wherein the first synthetic polymer is polypropylene, the second synthetic polymer is polyethylene terephthalate and the softening achieved by heating the composite to a temperature of about 180° to 280° C.

33. A method according to claim 1 wherein the first synthetic polymer is polyethylene terephthalate the second synthetic polymer is polyethylene and the softening is achieved by treating to a temperature of about 160° to 275° C.

* * * * *

June 8, 1965 A. GLICK 3,187,752

NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING

Filed April 27, 1962

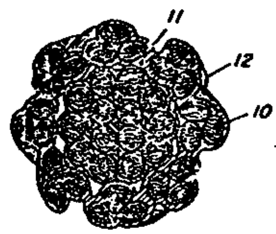

Fig. 1

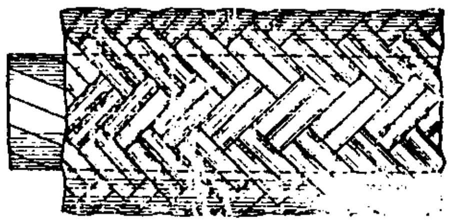

Fig. 2

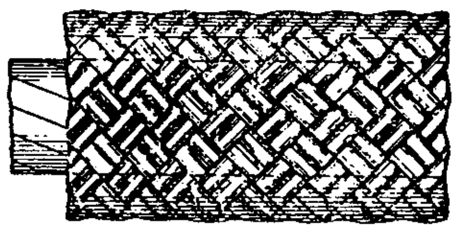

Fig. 3

INVENTOR
ARTHUR GLICK
BY
Samuel Branch Walker
ATTORNEY

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NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING

Arthur Glick, Danbury, Conn., assignor to American Cyanamid Company, Stamford, Conn., a corporation of Maine

Filed Apr. 27, 1962, Ser. No. 190,604
26 Claims. (Cl. 128—335.5)

This application is a continuation-in-part of application Serial Number 767,502, filed October 16, 1958 and now abandoned.

This invention relates to a non-absorbable densely constructed suture built up of a plurality of filaments having a serum-proof, moisture-resistant coating on the surface of the individual filaments, which coating contains a silicone resin.

As used in this specification the term "suture" is intended to include both sutures, as are used for the sewing of tissues, and ligatures as used for tying off blood vessels, etc. Different portions of one strand may be used for both purposes in the same operation depending upon the needs of the surgeon at the particular moment.

In surgical practice; and for present purposes, this includes both human and animal surgery, two classes of sutures are commonly used. One is the absorbable suture which is absorbed by the tissues and accordingly loses its identity, such sutures usually being of catgut, etc.; and the other form is a non-absorbable suture which in most instances is permitted to remain as such permanently in the tissues, but which is sometimes removed from the tissues at an appropriate phase of the healing process. Such non-absorbable sutures must be strong and should maintain their strength and integrity for prolonged periods while in contact with body tissues and fluids. It is desirable that such sutures be inert, causing a minimum of tissue irritation, and that the diffusion of fluids through the suture by capillarity be at a minimum.

It has been customary to use silk sutures built up as by braiding, weaving, twisting or spinning, hereafter called coordinate configuration, of a plurality of individual silk filaments. Synthetic polymers may be used instead of natural silk. These filaments represent a construction in which there are fine interstices which by capillary action cause fluids to travel along the length of the suture. This may permit migration of pathogenic organisms.

Accordingly, such sutures have been coated with waxes, such as beeswax, or beeswax mixed with ethyl cellulose, which material reduces the capillarity of the suture and improves the handling characteristics of the suture.

There is some evidence that under some conditions these waxes cause granuloma formation, and have other undesirable side effects.

Additionally the coating material should be inert to all body fluids and heat stable to permit heat sterilization of the suture. It is desirable that the coating be economical and readily applied.

In addition to the physiological properties of inertness the characteristics of handling and of strength of a suture are extremely important. It is desirable that a suture be sufficiently stiff that it can be easily handled and yet readily formable to a new position. After being bent to a new position, it should maintain this new set position. Many fibrous materials have a plastic "memory," and after being bent to a new position slowly on standing tend to go back to their former shape. A suture should not have plastic "memory" but should when once set maintain that new position.

2

Additionally the suture should be easy to tie into a knot and should be resistant to knot-slippage under strain and the knot should remain secure and not slip or untie itself on standing. Additionally, a suture should have what is known as "throwability." That is, the surgeon should be able to pick up the suture and throw it into a new position, which position is then retained. It is desirable at times to place a suture in a given location or throw it in a given direction with the knowledge that the suture will stay there until positively moved.

In the past a great deal of the handling characteristics have been imparted to a limp suture by the coating material. Beeswax or beeswax mixed with ethyl cellulose used as a coating is responsible for the desirable handling characteristics.

If some other coating material is used with the same filament construction, the sutures may not have satisfactory handling characteristics.

It has now been found that by braiding a suture with a tighter and more dense construction using fewer picks, i.e. cross-overs per inch, and by dry stretching the braided filaments, a suture can be formed which has inherently stiffer qualities and improved handleability.

Silk is the usual material used for non-absorbable sutures. Synthetic filaments such as nylon, polypropylene, "Orlon," polyacrylonitrile, "Dacron," a stretched oriented polyester of ethylene glycol and terephthalic acid, etc., or cotton, or linen are sometimes used. Occasionally such materials as stainless steel or horsehair are used. All such materials can be advantageously coated with polymeric silicones, in accordance with this invention, and are braided or spun or formed more tightly for coating with silicones than with conventional coating materials.

Polymeric silicones are applied to this denser suture; such polymeric silicones readily coat the individual filaments increasing the resistance to aqueous fluids thus reducing capillarity. Furthermore, such silicones applied as a coating are heat stable. In at least some instances the coating may be applied in a partially polymerized state and the silicone further polymerized in position on the suture. Fortunately and fortuitously, polymerization catalysts are decomposed by heat sterilization procedures or heat curing so that even if toxic catalysts are used as a component of the silicone coating, the final product is completely inert.

The particular silicone resins themselves are not a part of this invention and standard commercial resins may be used. It is not necessary that the material be applied as a liquid, as some of these silicone resin forming materials, such as the General Electric "Dri-film," are volatile and may be applied in the gaseous phase. These materials are among the volatile silicone compounds such as alkyl silicone halides. A material such as dimethyl silicone dichloride is comparatively volatile and may be applied either direct or by allowing an ethereal solution thereof to evaporate and the vapors contact the suture material.

Frequently, it is more convenient to use a liquid preparation. Such preparations are solvent dispersions of "silicone resins," that is partially polymerized products which will polymerize to a silicone film. For purposes of convenience it is normally easier to purchase the material under trade-names rather than making it, or obtain it to a performance specification. Materials which are sold commercially such as the Dow-Corning silicone "DC 803" or "DC 804" or General Electric's "9980" give highly satisfactory and useful films. To those skilled in the art of silicone compounding it is comparatively simple to select a heat-curable or potentially heat-curable silicone resin, which either from its inherent characteristics or

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000088

the addition of a polymerizing catalyst, will set up or cure. As a final check to insure the complete removal of all halide to silicone linkages, ammonia fumes may be used. Usually sufficient-moisture is present to insure the hydrolysis of the halogen, but ammonia fumes insure a neutral product. If desired, silicone containing resins may be used in which the silicone atoms are linked through nitrogen, from ammonia, rather than through oxygen as in the silicones, such resins at times being referred to as silamines.

Methods for preparation of silicone resins are well known. Patent No. 2,306,222 to W. I. Patnode, "Method of Rendering Materials Water Repellant," discloses the use of a vapor of an alkyl silicone halide for making glass vapor-proof. The same types of materials as therein described may be used to water-proof and treat sutures. The patent to Safford, No. 2,424,853, and the patent to Tanis, No. 2,408,822, additionally describe siliceous halides and their conversion to resins. There are several methods of preparing such silicone resins, among others are the reaction of Grignard type reagents with a silicone tetrahalide. From the standpoint of costs silicone tetrachloride is normally used and the Grignard may be either alkyl or aryl or a mixture thereof. The amounts of alkyl and aryl groups used affect the brittleness and rate of cure of the resin formed. Normally the product of the reaction of the Grignard reagent with silicone tetrachloride is allowed to react with moisture, allowed to partially polymerize, and the partially polymerized materials are dissolved in a suitable solvent whereby additional polymerization is either inhibited or substantially slowed down. The higher the ratio of lower alkyls, the more rapid the materials will cure and the more brittle will be the film. The more highly branched the chains formed in the resin, which are necessarily formed by the polymerization of the silicone types containing more halide atoms per silicone molecule, the more brittle and polymerized are the resins.

The organo-silicones sometimes referred to as organopolysiloxanes, more particularly the hydrocarbon substituted polysiloxanes are particularly suitable for suture coating. The patent to Wright et al., No. 2,389,477, entitled "Polysiloxane Resins" gives considerable information of this type of resin. Certain of the resins which are described in the patent to Hyde, No. 2,386,466, "Insulated Conductor and Insulation Therefor," if diluted with a solvent may be used in accordance with the instant invention. The patent to Hyde, No. 2,371,050, "Organo-Silicone Polymers and Method of Making Them," describes certain additional methods of preparing such resins. It is not necessary that the resins be prepared from halogen containing compounds as, for example, methods such as set forth by Strain et al. in Patent No. 2,394,642, "Silicic Acid Esters," describes a different form of silicone containing resin. The patent to Iler, No. 2,395,550, "Modified Alkyd Resins," describes still further modifications of silicone containing resins in which the silicone linkages are different than those classified as organo-polysiloxanes.

It is not intended that a treatise be here included on the production of such resins, as such resins are the invention of others and are adequately described in the patent literature, as well as elsewhere. The texts "Introduction to the Chemistry of the Silicones," Eugene G. Rochow, John Wiley & Sons, Inc., New York, 1946, and "Silicones and Their Uses," Rob Roy McGregor, McGraw-Hill Book Company, New York, 1954, give many useful details.

A pamphlet "Silicones in Medicine and Surgery," Rob Roy McGregor, Dow-Corning Corporation, 1957, discloses some of the silicones which may be used, and other medical usages for such silicones.

The silicone acts as a protective layer on the surface of the filaments, and prevents dyes or the surface characteristics of the filaments, such as silk, from interacting with body fluids. In neural surgery, suture materials frequently deleteriously affect regeneration of nerve fibers. Silicone coated silk is the first material known to have been successfully used in suturing nerve fibers which permits the regeneration of the nerves in the spinal column.

Usually silk is braided loose enough for a beeswax coating to impregnate the silk, reduce capillarity, and impart desirable handling qualities. The new silicone coating may not inherently have enough body to give the desired handling qualities. Rather than use a more highly polymerized silicone resin, which is stiffer, it is preferred to use a denser silk construction, with more silk filaments in a given cross-section. This gives a greater strength, and a thinner silicone coating gives a proper inertness to the suture and at the same time prevents capillarity.

One standard test for capillarity is to boil two 3 to 4 inch lengths of the suture in distilled water in a glass container for three successive 20-minute periods, changing the water each time. After the third boiling, the test sutures are allowed to stand for at least 8 hours in an atmosphere having a relative humidity of 65% ±2% at a temperature of 21° ±1° C. The segment of suture is tied to a piece of white silk thread with a square knot, the ends cut close, and suspended by the white silk thread so that the suture dips into a 0.5% aqueous solution of methylene blue, with the knot ¾-inch above the dye solution. After standing for 24 hours, the white silk is inspected for evidence of dye carried up the suture by capillary action. If the white silk is free from dye color, the suture is non-capillary, and passes the test. Both of the duplicate samples should pass.

Sutures of this invention pass this test for capillarity. Sutures which pass this test are non-capillary in tissues of man and animals.

For preventing slippage at knots in the suture, a coating forming a hardened, but flexible silicone film is preferred, using a silicone having a higher ratio of aryl groups. For instance, a polysiloxane having from about 72% to 67% methyl substituents and from 28% to 33% phenyl groups cures to a non-slipping finish that gives excellent knot retention. Usually the suture breaks before the knot slips. Also such polysiloxanes are sufficiently adhesive that spun sutures of silk or other filaments do not unravel, or "broom," and can be threaded into needles.

The silk construction itself rather than the coating can be used to give the handling qualities.

Whereas the number of ends, and total denier, varies with size, it is desirable that a maximum size, and strength be obtained within the overall limits of suture diameter. For the standard United States Pharmacopeia sizes (United States Pharmacopeia Convention, Inc., Distributed by Mack Publishing Co., Easton, Penn., elsewhere abbreviated U.S.P.) this is:

U.S.P. size	U.S.P. diameter, inches, max.	Picks per inch	Denier of raw silk used
6-0	0.004	40	172
5-0	0.006	49	282
4-0	0.008	43	378
3-0	0.010	48	630
00	0.013	50	928
0	0.016	52	1500

The picks per inch are the number of threads, running in one direction, per lineal inch of suture.

The silk is braided using a smaller number of picks than conventional, and with a larger core size. The braided silk is washed to degum, then dyed, if desired, in skeins in accordance with conventional practice. The silk is dried, and then dry stretched from about 6% to about 11% of its length. This stretching tightens the braid, and gives a more dense, more handleable silk. At least some of the stretching may be accomplished while the silk is wet.

After stretching the silk suture is passed through a solvent bath containing the polymeric silicone. Such solvents as xylene; toluene, benzene, gasoline, or other non-toxic volatile hydrocarbon solvents may be used. In addition to the silicone, beeswax, ethyl cellulose or a low molecular weight polyethylene may be dissolved and used as part of the coating. For the silicone rubbers, a catalyst is usually used to accelerate the curing rate. The standard organic peroxides, of which benzoyl peroxide is the most frequently used, are suitable catalysts, 2% to 20% by weight of the polymer gives good results. The heat which sets the resin decomposes residual peroxides to give non-toxic products. For the hardened, flexible films, having a higher percentage of phenyl groups, heat alone can cure the silicone. Organo metallic driers such as zinc octoate, or iron stearate accelerates the cure. Non-toxic salts of metals with fatty acids are effective.

A 2% to 50% solids bath gives a satisfactory coating.

A 5% to 30% solids concentration in the bath results in easier operating control. A 20% concentration is usually preferred. While an adequate pick up with a single coating bath is obtainable, more uniform distribution and coating can be obtained by using two or more baths, with heat curing between coatings. A cure temperature of at least 150° C. for 30 seconds gives a cure, although longer times at lower temperatures, or a longer cure with less catalysts, etc. in accordance with standard practice in the silicone art may be used.

A total weight of coat of 2% to 20% by weight of the fiber gives good characteristics. This percentage is called the pick up.

The sutures are shown in the attached drawings:

FIGURE 1 is a cross-section of a silicone coated suture.

FIGURE 2 shows a portion of an eight carrier on a 16 capacity carrier braider formed braid.

FIGURE 3 shows a portion of a sixteen carrier braid.

EXAMPLE 1

A silk suture is braided, using 8 carriers, on a sixteen carrier braider, with 3 ends of 13 to 15 denier silk per carrier, and a core of 3 ends of 13 to 15 denier silk, and 40 picks per inch, giving the skipped braid of FIGURE 2. The raw silk used has a total of about 378 denier. (The denier is the weight in grams of 9000 meters of the strand.) The braided suture is washed to degum, then dried, while looped in skeins. The dry silk is stretched 9% of its length, which gives improved stiffness; and increases the density.

A silicone rubber sold as "Silastic 9711" by Dow-Corning is milled into sheets of about ¼-inch thick, and thereto while milling additionally is added 8.46% by weight of the rubber of a silicone fluid containing 50% by weight benzoyl peroxide (Luperco ASF). After milling for an additional 5 minutes, the sheets are cut into small pieces and soaked overnight in xylene. The swollen silicone is stirred to a cream-like consistency, then diluted to 20% solids, and stirred until uniform.

The braided silk is immersed in a trough of the silicone solution at room temperature, then wiped over a piece of white felt. The coated silk is passed through a three stage heating tunnel, so that the silk is heated for one minute each at 100° C., 125° C., and 150° C. The silk is spooled after air cooling.

This coating procedure is repeated. In the double coating, the silk is found to have picked up 15% by weight of the silicone coating.

The finished suture gauges 0.0077 inch in diameter and is a 4–0 suture.

A conventional braiding of a 4–0 suture gives about 60 to 70 picks per inch, and uses 8 carriers with 2 ends of 20–22 denier each, and no core. Such a silk suture has a total denier of about 336, and if coated with beeswax in accordance with conventional practice gauges .0083 inch.

Other characteristics for comparison are:

	Silk With New Silicone	Silk With Old Beeswax
Picks per inch	40	60
Gauge:		
Raw ... inches	.0076	.0081
Sterilized ... do	.0077	.0083
Straight pull sterilized ... pounds	2.17	2.[illegible]
Knot pull sterilized ... do	2.06	1.[illegible]
Pliability to bend, raw ... mgs	.107	.100
Stiffness—inches self support:		
Horizontal (sterile) ... inches	2.04	4.75
Vertical (sterile) ... do	4.08	4.13
Apparent density as braided ... gms./cc	1.127	0.927

The increase in strength after sterilization both straight and over a knot shows the new silicone construction to have marked advantages.

The suture is sterilized either by conventional autoclaving procedures, or by ethylene oxide gas, in accordance with commercial practice in the industry.

The individual silk filaments of the braid are shown at 10, the filaments of the core are shown at 11, and the suture has a silicone coating 12. FIGURE 2 shows the construction of a 000 suture, otherwise the same as above.

EXAMPLE 2

The coating of the suture of Example 1 is repeated using a 15% solids solution of a dimethy silicone polymer of the general formula $((CH_3)_2SiO)_n$ with 5% by weight of the polymer of benzoyl peroxide as catalyst. After two coatings, a readily handleable suture is obtained.

EXAMPLE 3

A multi-filament 4–0 sized silk suture braided as in Example 1 is washed and dyed black in accordance with conventional procedures. The suture is then dry stretched. An alkyl polysiloxane sold by General Electric as "Dri-film 88" is diluted with toluene to form a 10% silicone solids solution. The silk suture is immersed in the [illegible] solution of the silicone resin at 50° C., then drawn through a curing tunnel at a temperature of 130° C., and of such length as to heat the silk suture for two minutes. The suture may be heated longer, so as to sterilize the suture at this time after which it is steritely packed and handled until used by the surgeon; or after the two-minute heating, the suture may be reeled and packaged using clean but not sterile techniques and finally sterilized by dry heat after packaging and prior to sale, or just prior to use by the surgeon.

EXAMPLE 4

A 4–0 silk suture braided, washed, and dried as described in Example 1 is immersed in a 10% solids solution of the polymerizing silicone resin commercially known as Dow-Corning 804. This resin is a comparatively short chain silicone resin containing both phenyl and methyl substituents on the silicone atoms. The silk suture is immersed in the solution of the silicone, the excess wiped off with a piece of felt, and the coated suture cured by passing through a curing tunnel in which the coated silk is heated to 130° C. for three minutes. The silk suture may be sterilized by heating, as desired, but before use. About 12% by weight of the silk of the silicone remains in the coating.

EXAMPLE 5

The silicone rubber sold as Dow-Corning "Silastic 9711" is milled with 4.2% of benzoyl peroxide for five minutes, cut into small pieces, covered with xylene, and soaked overnight. The swollen material is stirred with additional xylene to obtain a 20% solids concentration. Braided silk prepared as described in Example 1 is passed through the silicone in xylene, wiped with a piece of white

felt, then cured for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk picks up about 10% by weight of silicone solids. The silk suture is heat sterilized before use. The thus prepared suture is used in operations to suture tissues after surgery. The suture is found to be satisfactory and causes a minimum of tissue irritation and deleterious after-effects.

A pigment or dyestuff may be added to the coating solution if desired. Such coloration of the coating is particularly useful for synthetic filaments which are difficult to color.

EXAMPLE 6

A multi-filament size 3-0 braided polyester suture was coated in two passes with a silicone rubber bath containing 17% silicone solids dispersed in xylene. The coating and curing procedure was as described in Example 5. The suture picked up 2.9% by weight of silicone solids. The polyester suture was non-capillary.

EXAMPLE 7

A multi-filament 2-0 silk suture was braided using 16 carriers each containing 3 end 15 denier silk; a core of 14 ends 20-22 denier silk; a pick count of 50; and a total denier of 966. The construction is of the type shown in FIGURE 3. The braided suture was coated with a methyl phenyl polysiloxane which contains about 72% methyl groups and 28% phenyl groups. The coating bath contained 35% silicone solids in xylol. The excess coating was wiped off with a piece of sponge rubber and the coating was cured for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk picked up 7% by weight of silicone solids for one coat. A second coat under the same conditions yielded a total pick up of 12%. The silk at both coating levels was non-capillary, had good bond and showed good resistance to brooming. Surgeon's knots tied in the silk broke before slipping.

EXAMPLE 8

A multi-filament spun, or twisted, 3-0 silk suture was coated with a methyl-phenyl polysiloxane, processed and cured as in Example 7. The spun and twisted silk had a silicone pick up that ranged from 7% for a single coat to 12% for a double coat. The silk did not broom or bush and the filaments were bonded together, so that a needle could be readily threaded.

EXAMPLE 9

A multi-filament size 3-0 braided nylon suture was coated in two passes in a silicone rubber bath containing 17% silicone solids dispersed in xylene. The coating and curing procedure was that described in Example 5. The nylon suture picked up 4.5% by weight of silicone solids and was non-capillary. Good results were obtained when used in surgery.

EXAMPLE 10

A multi-filament braided 3-0 suture was coated with a bath containing 30% solids of a silicone resin commercially sold as Dow-Corning 804. This resin is a comparatively short chain silicone resin containing both phenyl and methyl substituents on the silicone atoms. Added to this bath was a plasticizer amounting to 20% of the weight of the silicone solids. The silk was immersed in this bath, the excess silicone wiped off with sponge rubber and the silicone was cured in a tunnel for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk for a single coat had a silicone pick up of 7% of the weight of the silk. Silk with two coats had a pick up of 12% silicone resin. Silk coated in this resin bath and the added plasticizer had good hand, was non-capillary and did not broom. Plasticizers used were alkyl aryl phosphates, phthalates, sebacates, citrates, epoxies and polymeric dimethyl siloxanes.

The polysiloxanes containing larger proportions of aryl groups require larger amounts of plasticizers. The pick up can be readily varied by the pressure on the wipers. A slower cure at a lower temperature gives a good coating. A more rapid cure is generally preferred, as the cure most conveniently takes place in a tunnel, and if a slower cure is used the tunnel must be longer for a given production rate and hence is more expensive.

I claim:

1. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 6-0; picks per inch 40; denier of raw silk used 112; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

2. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 5-0; picks per inch 40; denier of raw silk used 252; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

3. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 4-0; picks per inch 40; denier of raw silk used 378; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillary and not more than 20% of the weight of the uncoated filaments.

4. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 3-0; picks per inch 40; denier of raw silk used 630; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

5. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 00; picks per inch 50; denier of raw silk used 966; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

6. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 0; picks per inch 50; denier of raw silk used 1560; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

7. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a xylene solution of a polymerizable silicone, wiping the braided silk suture, whereby there is a silicone pick up of about

10% to 20% by weight, and drying and polymerizing said silicone.

8. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a solution of a polymerizable silicone containing a catalyst, wiping the braided silk suture, whereby there is a silicone pick up of about 10% to 20% by weight, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

9. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in non-toxic volatile hydrocarbon solvent solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, drying and polymerizing said silicone, re-immersing in said solution, re-wiping the suture, whereby there is a total silicone pick up of about 10% to 20% by weight, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

10. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 6-0; picks per inch 40; denier of raw silk used 112; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

11. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 5-0; picks per inch 40; denier of raw silk used 252; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

12. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 4-0; picks per inch 40; denier of raw silk used 378; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

13. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 3-0; picks per inch 40; denier of raw silk used 630; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

14. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 00; picks per inch 50; denier of raw silk used 966; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

15. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 0; picks per inch 50; denier of raw silk used 1560; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

16. A surgical suture comprising a plurality of individual filaments in coordinate configuration, the filaments being bonded together to hold the filaments in a unitary strand, and hence non-brooming, having a coating on each filament of a non-toxic, physiologically inert, polymeric silicone, whereby the suture is non-capillary and is inert towards living tissue, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments.

17. A surgical suture comprising a plurality of individual filaments selected from the group consisting of silk, nylon, polypropylene and stretched oriented polyester, the external filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each filament of a non-toxic physiologically inert polymeric silicone, whereby the suture is non-capillary and is inert towards living tissue, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments.

18. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, whereby the suture is non-capillary and is inert towards living tissue, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments.

19. A surgical suture comprising a plurality of individual silk filaments in coordinate configuration, each filament having thereon a coating of a polymethyl-polyphenyl siloxane, at least the final polymerization being in situ, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments, whereby the suture is non-capillary and is inert towards living tissue, and the siloxane coating causes the filaments to adhere to each other, and thereby be free from brooming, and which suture, when tied in a surgeon's knot, breaks rather than slips, on pulling in tension.

20. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a xylene solution of a polymerizable silicone, wiping the braided silk suture, whereby there is a silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone.

21. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, whereby there is a silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

22. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 5 to 11% of its length, immersing the braided silk in non-toxic

volatile hydrocarbon solvent solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, drying and polymerizing said silicone, re-immersing in said solution, re-wiping the suture, whereby there is a total silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

23. A surgical suture comprising a plurality of individual filaments in coordinate configuration, the filaments being bonded together to hold the filaments in a unitary strand, and hence non-brooming, having a coating on each filament of a non-toxic, physiologically inert, polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

24. A surgical suture comprising a plurality of individual filaments selected from the group consisting of silk, nylon, polypropylene and stretched oriented polyester, the external filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

25. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

26. A surgical suture comprising a plurality of individual silk filaments in coordinate configuration, each filament having thereon a coating of a polymethyl-polyphenyl siloxane, at least the final polymerization being in situ, the weight of said silicone being an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and said suture is inert towards living tissue, and the siloxane coating causes the filaments to adhere to each other, and thereby be free from brooming, and which suture when when tied in a surgeon's knot, breaks rather than slips, on pulling in tention.

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RICHARD A. GAUDET, *Primary Examiner.*
JORDAN FRANKLIN, *Examiner.*

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000093

United States Patent [19] [11] **4,047,533**
Perciaccante et al. [45] **Sept. 13, 1977**

[54] **ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT**

[75] Inventors: Vincent Anthony Perciaccante, Long Island City; Henry Patrick Landi, Yorktown Heights, both of N.Y.

[73] Assignee: American Cyanamid Company, Stamford, Conn.

[21] Appl. No.: 724,804

[22] Filed: Sept. 20, 1976

[51] Int. Cl.[2] A61L 17/00
[52] U.S. Cl. .... 128/335.5; 128/1 R; 428/375
[58] Field of Search 128/1, 335.5; 428/275

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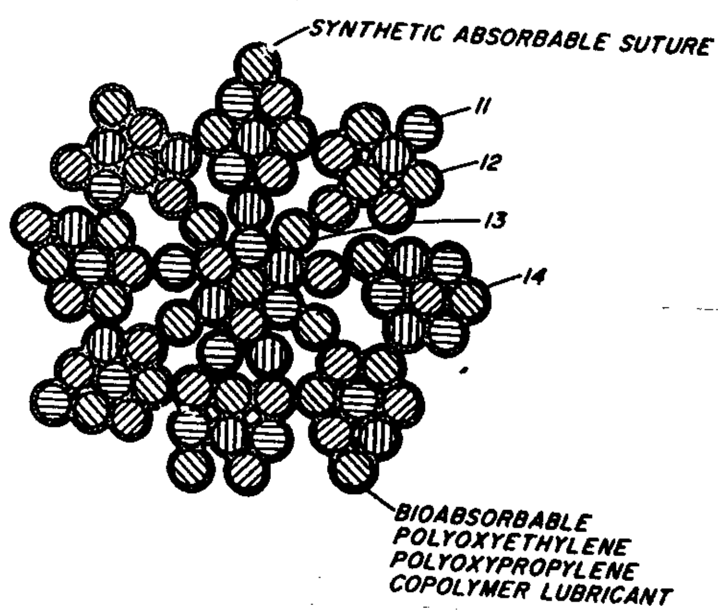
3,061,470	10/1962	Kuemmerer	428/375 X
3,432,898	3/1969	Stanley et al.	428/396 X

Primary Examiner—Leland A. Sebastian
Attorney, Agent, or Firm—Charles F. Costello, Jr.

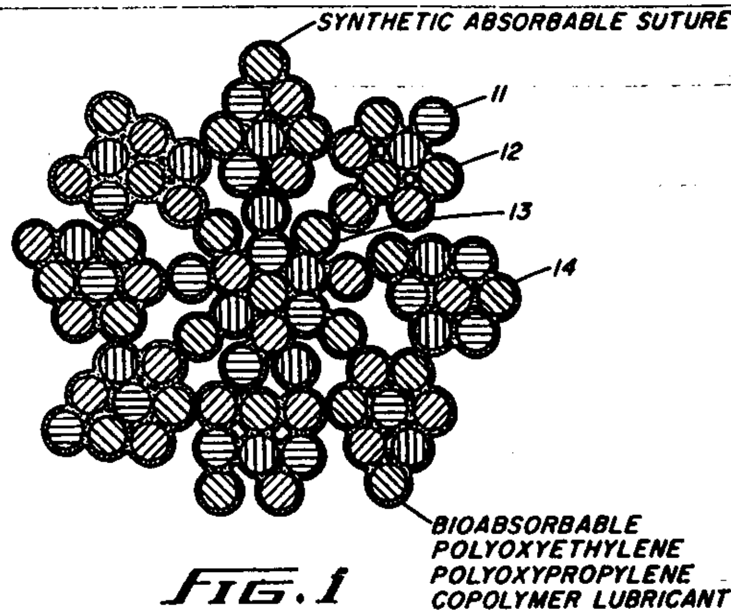
[57] **ABSTRACT**

The handling characteristics, including particularly the knot run-down, of synthetic absorbable surgical sutures and tissue drag characteristics are improved by a coating of a lubricating film of a bioabsorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks, and which bioabsorbable copolymer has a molecular weight such that it is pasty to solid at 25° C.

23 Claims, 2 Drawing Figures



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000094


SYNTHETIC ABSORBABLE SUTURE
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BIOABSORBABLE POLYOXYETHYLENE POLYOXYPROPYLENE COPOLYMER LUBRICANT

FIG. 1

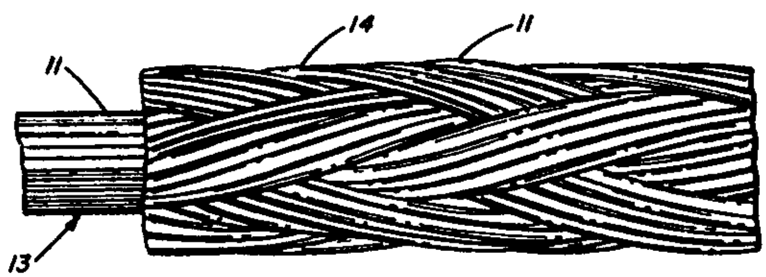
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FIG. 2

ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

BACKGROUND OF THE INVENTION

The handling characteristics of surgical sutures encompass many factors, some of which factors are at least in part inconsistent or seemingly inconsistent. There is a constant effort to improve the handling characteristics. Among the more important of the handling characteristics are those associated with knot run-down. In many surgical procedures it is necessary that a knot be tied in a suture when the knot is deep inside a surgical or natural opening. For instance, a dental surgeon may need to tie a knot inside a patients mouth. An intravaginal hysterectomy requires suturing in restricted quarters. One technique frequently used is to tie a square knot that can be run-down from an exterior location where the knot is first tied to lie against tissue with a desired degree of tightness. The knot is snugged down so that it is holding with a degree of firmness chosen by the surgeon for a particular situation and then additional throws are tied down against the first throws of the square knot. In some instances, the first throw is a double twist followed by a single throw to form a surgeons knot, with additional throws to form additional square knots on top as needed. As contrasted with the ease of placement, is the necessity of knot security. Each though it is desired that it be easy to tie a knot, it is mandatory that the knot hold without slipping for an acceptable length of time. With buried absorbable sutures, of course, the suture including the knot is eventually absorbed, and the knot need only hold until the tissue is adequately regenerated. This can be merely a few hours for certain types of skin incisions, up to requirements of the order of 15 to 28 days for many types of internal knots. If strength for a longer time or permanent reinforcement is needed, non-absorbable sutures may be used.

Some suture materials are so smooth that a knot runs down very readily and frequently becomes readily untied. Other sutures are of materials in which the knot tends to "lock-up" or refuse to run-down so that it is difficult to snug-down the throws against the tissue and only a few throws are needed, and security is not a problem. Knots in constantly moving tissue, such as adjacent to the heart, have a much greater chance of becoming untied than knots in quiescent tissue such as knots holding together a wound inside a plaster cast.

The problem of improving suture performance under varied conditions has been the subject of much research over a prolonged period.

PRIOR ART

U.S. Pat. No. 1,254,031 — Jan. 22, 1918, Davis, SUTURE AND METHOD OF MAKING THE SAME, shows a braided collagen suture immersed in collagen or glue to cause close adhesion of the braid, to fill up the interstices and provide a smooth uniform coating.

U.S. Pat. No. 2,576,576 — Nov. 27, 1951, Cresswell and Johnstone, LUBRICATED THREAD, shows a lubricated multifilament collagen thread using as a lubricating film a phosphatide such as lecithin. The lecithin should be applied at the time of coagulation or regeneration of collagen as effective lubrication is not

obtained if the lubricant is incorporated by adding to a finished thread.

U.S. Pat. No. 2,734,506 — Feb. 14, 1956 - Nichols et al. SILK SUTURES AND LIGATURES shows using poly(alkyl methacrylate as a coating for silk sutures, and a hot coating die system.

U.S. Pat. No. 3,187,752 — June 8, 1956 — Glick, NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING, shows silk or other non-absorbable synthetic filaments such as nylon, cotton or linen coated with a silicone which gives a more inert suture and reduces capillarity.

U.S. Pat. No. 3,209,589 — Oct. 5, 1965 — Schlatter, YARN FRICTION MEASURING INSTRUMENT, describes a machine for measuring the friction of a yarn sliding over itself and describes the variation of friction with speed, and the "slip-stick" variety at slow speeds.

U.S. Pat. No. 3,297,033 — Jan. 10, 1967 - Schmitt and Polistina, SURGICAL SUTURES, shows synthetic surgical sutures of polyglycolic acid and discloses that the surfaces of the fiber can be coated with a silicone, beeswax, or the like to modify the handling or the absorption rate.

U.S. Pat. No. 3,390,681 — July 2, 1968, Kurtz, POLYESTER SUTURE HAVING IMPROVED KNOTTING CHARACTERISTICS, shows improving the knotting characteristics of a polyester such as one formed from a dicarboxylic acid and a diol (Dacron) by depositing on the fibers a polytetrafluoroethylene (Teflon). This patent discloses many of the problems in suture knots, and is hereby incorporated by this reference hereto. This patent also shows the accepted practice of classing "ligatures" under "sutures" for patent disclosure purposes.

U.S. Pat. No. 3,565,077 — Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME, shows a suture construction using polyglycolic acid filaments with a compacted structure and a reduced void fraction.

U.S. Pat. No. 3,815,315, June 11, 1974, Glick, ETHYLENE OXIDE STERILIZATION OF MOISTURE SENSITIVE SURGICAL ELEMENTS shows the desirability of maintaining surgical elements of polymers subject to the hydrolytic degradation to non-toxic, tissue-compatible, absorbable components, such as polyglycolic acid sutures, in a desiccated condition in an air tight container impervious to moisture vapor. Suitable desiccating cycles and foil containers to give product which are storage stable for years are disclosed.

U.S. Pat. No. 3,867,190 — Feb. 18, 1975, Schmitt and Epstein, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, shows the coating of polyglycolic acid surgical sutures with a copolymer of from 15-85% glycolic acid with 85-15% lactic acid which coating fills the interstices of a multi-filament polyglycolic acid suture. Example 10 discloses the coating as minimizing capillarity, and improving run-down. Thicker coatings increase stiffness. This patent has 38 references to earlier prior art on sutures and methods of making them, and related fields and is incorporated herein by this reference thereto. A divisional of said 3,867,190 is Ser. No. 489,004, July 16, 1974, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, now U.S. Pat. No. 3,982,543 dated Sept. 28, 1976.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000096

U.S. Pat. No. 3,896,814 — July 29, 1975 — Vivien and Schwartz, COLLAGEN BASED THREADS, shows a collagen or catgut thread which is flexibilized by having therein water and a hygroscopic agent such as a glycerol or a glycol or a low molecular weight (up to 400 m.w.) liquid polyalkalene oxide, and which may additionally be coated with a lipoid or a silicone for surface lubricity.

U.S. Pat. No. 3,942,532 — Mar. 9, 1976 — Hunter and Thompson — BRAIDED SUTURE, discloses an adaptation of an INSTRON Universal Testing Instrument using an oscillographic recorder, to use a single throw between two suture strands to measure surface roughness, as an indication of the ease of sliding a single throw knot down the suture into place, there called "tie-down performance". A coating of 0.4 percent to 7 percent of the suture weight of an aliphatic polyester such as a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000–3,000 is recommended.

U.S. Ser. No. 691,749, filed June 1, 1976 — Casey and Epstein — NORMALLY-SOLID BIOABSORBABLE, HYDROLYZABLE, POLYMERIC REACTION PRODUCT, discloses the use of transesterification product of poly(1,4-propylene diglycolate) and polyglycolic acid and other trans-esterification products of polyglycolic acid and a polyester of diglycolic acid and an unhindered glycol to coat sutures to improve knot run-down and other suture characteristics.

The coating, coloring and conditioning of surgical sutures with polymeric materials in general is well-known. Silicones, wax, polytetrafluoroethylene, and other polymers have been used. Specific coating materials with unique advantages to give improved sutures are constantly being sought.

SUMMARY OF THE INVENTION

It has now been found that the knot run-down characteristics, handleability, tie-down performance and tissue drag characteristics of braided, twisted or covered multifilament synthetic absorbable sutures may be improved by coating with a lubricating biologically absorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks.

Absorbable polyglycolic acid sutures are described in U.S. Pat. No. 3,297,033, supra. Other synthetic absorbable sutures which absorb in living tissue may be coated with improved results. At present absorbable sutures meeting with market acceptance are those in which the degradation or absorption in tissue results from the hydrolytic degradation of glycolic acid ester linkages. Such materials are presently being sold under the trademarks DEXON® and VICRYL®. The present invention may be used with other synthetic absorbable surgical sutures, described in the prior art, and as they are developed. With synthetic absorbable sutures the problem of a coating to improve knot run-down characteristics is made more difficult by the requirement that the coating must be non-toxic and absorbable.

Absorbable or bioabsorbable as applied to the coating, refers to a coating which by hydrolytic or enzymatic degradation, or by its inherent characteristic, has such molecular weight and solubility properties that it is absorbed from the surface of the suture and is eliminated by the subject either unchanged or in hydrolyzed or degraded form. The exact mechanism of the disposition of the coating in mammalian tissue is not critical to the understanding of the present invention, as long as the coating is non-toxic.

It is also found that the lubricant coating not only aids in the knot run-down characteristics but increases the smoothness and flexibility of the sutures so that they may be more easily drawn through the skin and other tissues during placement of the suture. This reduction in friction is called reduced tissue drag.

Another unexpected and unobvious advantage of the present lubricant coating in that the lubricant copolymers are absorbed from the suture within a few days. The coating that aids in friction reduction in tissue drag and lubricates in knot placement also causes the knot to slip more readily. When the lubricant is comparatively rapidly absorbed in living mammalian tissue, the resistance of the knot to slippage or untieing due to tissue movement is soon increased. As the wound heals the knot security actually improves, up to the time that the synthetic absorbable suture loses strength preliminary to absorption.

The absorbable coating is one or more of a group of compounds having blocks of polyoxyethylene and blocks of polyoxypropylene in their structure. For simplicity and ease of description these compounds are taught, drawn and treated as if there were merely two or three blocks in the chain. However, it is to be understood that non-significant qualities of polyoxypropylene may be present in the polyoxyethylene block and minor quantities of polyoxyethylene may be present in the polyoxypropylene block. From the methods of manufacture it would appear that there may be and probably are such minor admixtures present in the chain. The commercially available grades are acceptable and found to have a low and acceptable degree of toxicity.

The present lubricants may be indicated as having the formula:

$$R[(CH_2\underset{R_1}{\underset{|}{CHO}})_n(CH_2\underset{R_2}{\underset{|}{CHO}})_mH]_c$$

where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R. Those compounds which are at least pasty at 25° C. are preferred because they adhere better to the synthetic absorbable polyfilamentary suture. There is not a sharp cut off, but in general as the materials become more pasty or solid, their effectiveness improves.

The lubricant compounds and methods of manufacture are described at length in certain prior art. The Pluronics in general are described in U.S. Pat. No. 2,674,619, Apr. 6, 1954, POLYOXYALKYLENE COMPOUNDS, L.G. Lundsted. These are referred to as a cogeneric mixture of conjugated polyoxypropylene-polyoxyethylene compounds and are further described therein.

Certain nitrogen containing polyoxyethylene detergent compositions which are here useful as lubricants are described in U.S. Pat. No. 2,979,528, Apr. 11, 1961, NITROGEN-CONTAINING POLYOXYALKYLENE DETERGENT COMPOSITIONS, L.G. Lundsted. Column 4, lines 44–58 of this patent disclose

that the oxypropylene chains may have a small amount of ethylene-oxide therein and vice versa. Because of the sources of ethylene oxide and propylene oxide, usually from petroleum fractions, it is to be expected that in commercial practice complete rectification to chemically pure compounds is not obtained. Fortunately the commercial grade may be used on absorbable sutures with excellent results. Said 2,979,528 also points out that as polymers, all molecular species are far from identical—some chains are shorter, some are longer, but on the average the materials are as indicated and it is the physical properties of the lubricants, not the molecular weight spread of the components, which are important.

U.S. Pat. No. 3,036,118, May 22, 1962, MIXTURES OF NOVEL CONJUGATED POLYOXYETHYLENE-POLYOXYPROPYLENE COMPOUNDS, D. R. Jackson and L. G. Lundsted, has much disclosure on the addition of polyoxyethylene groups and polyoxypropylene groups to reactive hydrogen compounds having from 2 to 6 reactive hydrogen atoms and not over 6 carbon atoms per molecule. Among other such compounds are listed the group consisting of aliphatic polyhydric alcohols, alkylamines, alkylene polyamines, cyclicamines, amides, and polycarboxylic acids, oxyethylene groups and oxypropylene groups. The reactive hydrogen compound serves as a chain initiator and can be present in such a small proportion that it has minor significance in its own right and serves mainly as a foundation on which the predominantly polyoxyethylene or polyoxypropylene blocks may be added in the chosen order. Whereas Patent 3,036,118 claims primarily the Reverse Pluronics in which the polyoxy-ethylene chains are attached to the nucleus or initiating reactive hydrogen compounds, in the present invention either the Reverse Pluronic with the polyoxyethylene in the center or the regular Pluronics with the polyoxypropylene in the center or the Tetronics with nitrogen in the center may be used for lubricant purposes.

Because the chemistry is previously known, and to avoid unnecessarily extending the length of the present disclosure, the disclosures of each of these three patents is herein hereby incorporated by this reference thereto.

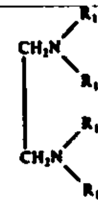
These lubricating bioabsorbable copolymers are often classed as surface active agents as the polyoxyethylene blocks are predominantly hydrophylic and the polyoxypropylene blocks are predominantly hydrophobic. The materials have been sold by the Wyandotte Chemical Company under the trademark of PLURONICS for the formula:

$$H(OCH_2CH_2)_x(\underset{\displaystyle CH_3}{\underset{|}{O CHCH_2}})_y(OCH_2CH_2)_zOH$$

where *x*, *y* and *z* are whole numbers. REVERSE PLURONICS for the formula:

$$H(\underset{\displaystyle CH_3}{\underset{|}{OCHCH_2}})_n(OCH_2CH_2)_m(\underset{\displaystyle CH_3}{\underset{|}{OCHCH_2}})_oOH$$

where *n*, *m* and *o* are whole numbers and TETRONICS for the formula:



where R_1 is

$$-(\underset{\displaystyle CH_3}{\underset{|}{CH_2CHO}})_q(CH_2CH_2O)_rH$$

where *q* and *r* are whole numbers.

For the present purposes as synthetic absorbable suture lubricants, the values of *x*, *y*, *z*, *n*, *m*, *o*, *q* and *r* are such that the lubricants are pasty to solid at 25° C.

The pastes are opague semi-solids with melting points above room temperature—preferably above about 40° C.

Those classed as Pluronics are particularly useful for the present invention.

The physical characteristics of these lubricant compounds are affected by their total molecular weight and by the percentage of polyoxyethylene in the molecule. References are made to the commercially available compounds for purposes of convenience. Those which are liquid normally have an L as a primary designator, those which are pasty have a P and those which are solid have an F. For the Pluronics, the first number indicates the typical molecular weight of the polyoxypropylene hydrophobic portion with a number 3 being about 950; 4 being about 1200; 5 being about 1450; 6 about 1750; 7 about 2050; 8 about 2250; 9 about 2750; 10 about 3250; 11 about 3625 and 12 about 4000. The second digit indicates the approximate percentage of the polyoxyethylene hydrophylic units in the total molecular, in units of 10. Thus for example, the formulations of certain commercially available products is approximately that shown in Table I.

As all compositions are mixtures, all values are approximate, and values are subject to some rounding.

Additional data is given in The Journal of the American Medical Association, volume 217, pages 469 to 470 (1971) where the new nonproprietary name of POLOXAMER is established for these compositions as direct food additives.

TABLE I

PLURONIC	Average Molecular Weight	M.W. of each Polyoxyethylene Block	Units of each x and z	% Polyoxy-ethylene	M.W. of Poly-oxypropylene Block	Units of y	M.P. ° C.
F-38	5000	2000	46	80	930	16	45
F-68	8350	3300	75	80	1,750	30	52
F-77	6600	2300	52	70	2,050	35	48
P-85	4600	1200	27	50	2,250	39	40
F-87	7700	2700	62	70	2,250	39	49
F-88	10800	4300	97	80	2,250	39	54
F-98	13500	5400	122	80	2,750	47	55
F-108	14400	5600	128	80	3,150	54	57

TABLE I-continued

F-127	12500	4300	98	70	3,900	67	56

REVERSE PLURONIC			M.W. polyethylene units of m block		M.W. polyoxypropylene block		Units of n and O
10R8	3,000	2000	45	65%	562	9	46
17R8	4,350	2600	39	60%	870	15	33
25R8	9,000	3250	74	57%	1,250	22	56

TETRONIC	Average Molecular Weight	Approximate Molecular Weight of Individual Polyoxyethylene Block	Approximate % Polyoxyethylene	Molecular Approximate Weight of Individual Polyoxypropylene Block	Approximate Polyoxypropylene	Average Approximate length of chains per block: Units of r	Average Approximate length of chains per block: Units of q
707	12,000	2312	74	673	26	52.5	11
908	26,100	5588	85	923	15	127	15.9
1107	14,500	2438	67	1173	33	55.4	20.2
1307	18,600	3213	69	1423	31	73	24.5
1508	27,000	5063	75	1673	25	115	28.5

In general, the Pluronics with a molecular weight range of from about 4,750 to 16,250 are waxy solids. The polyoxypropylene portion has a molecular weight of 950 to 4,000 and the polyoxyethylene content of about 60-80%.

The pastes in general have a total molecular weight ranging from 3,500 to 5,700 with a polyoxypropylene molecular weight range of 1,750 to 6,500 and polyoxyethylene content of 30 to 50%. The transitions from wax to paste to liquid are not sharp.

COATING

The synthetic absorbable suture is conveniently coated by several conventional procedures including:

Melt Coating

The uncoated suture is placed in a split die whose orifice corresponds to diameter specifications for the particular size suture to be coated. The die is then clamped in a heating block and the polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer placed in the die. The die is raised to a temperature about 20° C. above the melting point of said copolymer and after the copolymer has melted, the suture to be coated is slowly pulled downward through the molten material in the die and collected on a take-up spool. The spool is mounted directly below the die a sufficient distance to allow solidification of the coating. A cooling tunnel or a blast of cooling air may be used to increase production speeds. Nichols et al. 2,734,506, supra, describes one useful apparatus for coating.

Solution Coating

The polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer is dissolved in chloroform. About twice the percentage by weight is used for coating solution as is desired on the final sutures. A feed loop such as a loop of wire or a ceramic is threaded with the uncoated suture, after which the feed loop is then submerged in the solution and the suture is passed down through the feed loop. It may be passed through a die whose diameter is such that after drying a suture will have the desired diameter. The suture is pulled slowly through the solution and at least partially dried in a drying tunnel. The drying is finished after the suture is wound on a spool. Because variations in equipment, speed, and temperature affect the pick-up of the lubricant bioabsorbable polymer, the concentration in the coating is adjusted based on a preliminary run or experience.

During the following the application of the coating to the synthetic absorbable sutures, contact of the filaments with moisture, or water vapor is minimized. The final coated suture is thoroughly dessicated before packaging in a moisture proof container, such as a metal foil envelope, for long term storage stability. U.S. Pat. No. 3,814,315 supra, discloses methods of dry packaging and sterilizing, and is hereby herein incorporated by this reference thereto.

Other coating techniques which are well known in the coating of polyfilamentary strands may be used. The techniques used for insulating wire may be adapted for large scale suture manufacture. The above are merely two of the more convenient and well known methods for coating. Details are later illustrated in examples.

Toxicity

The low toxicity of the polyoxyethylene-polyoxypropylene compounds of the present invention are shown in such U.S. Pat. Nos. as 3,450,502 which describes the use of a copolymer having a total molecular weight of about 8,750 in isotonic solutions used as a priming agent in a heart-lung apparatus. In sutures even if a maximum of around 25-30% by weight of the suture of copolymer is used, only a very small amount is placed in the subject.

The low toxicity is shown in the following table.

TABLE II

TOXICITY

Pluronic No.	Total Molecular Weight	Physical Characteristic	LD 50 (gm/kg) in Mice
F-38	5000	wax	> 5
F-77	6600	wax	4.2
F-87	7700	wax	3.75
F-68	8350	wax	> 5
F-88	10800	wax	> 5
F-127	12500	wax	2.25
F-98	13500	wax	> 5
F-108	14400	wax	1.25
P-65	3400	paste	0.83
P-84	4200	paste	0.4
P-85	4600	paste	0.53
P-94	4600	paste	0.6
P-103	4950	paste	1.4
P-104	5850	paste	0.75
P-123	5750	paste	2.7
P-105	6500	paste	3

The polyoxyethylene-polyoxypropylene compositions used as the lubricant bioabsorbable copolymers have been used in food products; and have been the subject of studies as to their elimination from a mammalian body. In general, they are eliminated in the urine fairly rapidly, and within 48 hours nearly all have been eliminated from the blood stream.

If some of the lubricant bioabsorbable copolymer is trapped in braid pores of a suture, the rate of diffusion into the blood stream may be reduced and hence the

time for elimination somewhat increased. The molecular weight is small enough that the lubricant bioabsorbable copolymers may be eliminated unchanged, although some degradation may occur before elimination. The important thing is that the lubricant bioabsorbable copolymer has no deleterious effect upon healing tissues adjacent to the sutures, and being removed from the surface of the suture by absorption by the body, knot security is improved. As soon as suture placement is completed, the knot run down and tissue drag reduction function is complete, and as the lubricant bioabsorbable copolymer is removed from the suture, knot security improves.

Definitions in the suture and textile trades are sometimes ambiguous or confused. As herein used;

A "filament" is a single, long, thin flexible structure of a non-absorbable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a longer continuous thread.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

The term "suture" is used to include the term "ligature" as technically a suture is used with a needle whereas the ligature is merely used to tie without being placed by a needle.

A finished suture has a needle attached and is sterile and ready for use in surgery. For purposes of convenience in nomenclature, the term "suture" is frequently used to refer to the same strand before it is coated and before it is packaged and sterilized. Context indicates whether it is the sterile suture ready for use, or the suture in a manufacturing step which is referred to.

The strand of the suture is used as the basis for weight in determining the quantity of material that is placed on the synthetic absorbable polymer strand in forming the absorbable surgical suture.

The quantity of the lubricating bioabsorbable copolymer is from about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer based on the weight of the uncoated strand forming the suture. It is not necessary that the coating be continuous as a discontinuous coating on the surface aids in reducing friction and chatter. A larger quantity may be present if the lubricating bioabsorbable copolymer penetrates inside the strand, with the various filaments themselves being partially or totally covered.

The wide range of coating weight permits adaptation of the present sutures to many varied uses. Because the strand to be coated to form the suture may have considerable variation in surface roughness, due to the mechanical structure, i.e. braid or twist, etc. as well as being made from filaments which are less than 2 denier per filament to more than 6 denier per filament, with the finer filament sizes giving a smoother surface; and because the filaments may be stretched after the suture is manufactured or in heat treatment, the surface roughness basically can vary. The smoother surfaces require less of the lubricating bioabsorbable copolymer for analogous degrees of slippage.

The various surgical techniques used interact with the desired degree of lubrication. For any given type of knot, a larger quantity of lubricant which for a particular technique increases the ease of run-down, also increases the ease of the knot running back or slipping, called knot security. For some surgical procedures it is highly desirable that the knot be very free in running down, even though the knot slips more readily.

A surgeon in tying knots is confronted with the interaction between the method of tying the knot and the ease of slipping. If a suture is comparatively well lubricated, the surgeon can use a square knot, which is run down readily; with additional squared throws for knot security. On the other hand, if the suture is less well lubricated, the surgeon can use a double half-hitch or some other type of knot which moves more readily to run the knot down to position, after which the double half hitch can be pulled to square the knot, or additional throws can be thrown down against the knot to give adequate knot security. Thus the surgeon can either adapt his knot technique to a particular suture, or can get sutures whose surface lubricity is best adapted to the technique which the surgeon desires to use. Generally, there is an adaptation of each to the other. The surgeon attempts to get a suture whose characteristics are those which he prefers, and then adapts his knot tying techniques to the sutures that he has at the time. Some surgeons make very successful knots with stainless steel wire using a knotting technique that is adapted to such a wire which has very poor run-down. Others prefer a much more readily run-down well-lubricated suture.

Additionally the location of use has influences. Sometimes a suture in passing through tissue picks up tissue fluids. The suture may be coated with tissue fluids which are either fresh or partly dry at the time the knot is tied. In some surgical techniques it is necessary to preplace the sutures, and tie the suture after the coating of tissue fluids on the suture has a chance to become at least partially dried.

Because the ease of knot run-down and knot security are somewhat opposite, it is necessary for the surgeon to use additional throws or such knots as will hold under the particular conditions of a selected surgical procedure. By changing the quantity of the lubricant bioabsorbable copolymer, the run-down can be modified to suit a using surgeons preference.

The time of use of the knots can be quite varied. Some surgeons use a suture to ligate bleeders in a wound with a retention requirement of 30 minutes or less. Such knots can be removed as the surgical procedure is complete, and before wound closure. Others leave the absorbable knots in the tissue even though there is no likelihood that a bleeder would reopen. For such usage, a suture which retains strength for 30 minutes is adequate. For wound closure and some other uses, it is desired that the synthetic absorbable suture maintain strength for at least 15 days to 4 weeks.

Because the present lubricating bioabsorbable copolymer is removed from the suture in living tissue, as the lubricant is removed the knot security increases and after 48 hours more or less, knot security is greatly improved.

The examples following should show the effects of certain different coating and quantities under certain conditions.

The requirements of surgery are extremely varied, and various coating weights permit adaptation of synthetic absorbable sutures to different conditions.

In general, if the surgeon desires a better lubricated suture, a larger quantity of the lubricating bioabsorbable copolymer is used and conversely if the surgeon in willing to accept slightly reduced knot run-down and tissue drag characteristics in favor of greater knot security, the coating level is reduced in favor of this particular compromise.

Usually from 2 percent to 8 percent of the lubricant bioabsorbable copolymer gives a useful range of compromise between the ease of knot run-down and knot security.

A usage of about 5 percent by weight of Pluronic F-68 is a preferred compromise between the knot run-down and knot security requirements for 2 to 6 denier per filament braided sutures of polyglycolic acid.

In the Drawings:

FIG. 1 is a cross-section of a synthetic absorbable suture having on the surface thereof a bioabsorbable polyoxyethylene polyoxypropylene copolymer lubricant.

FIG. 2 is a drawing of a suture showing the parallel filaments in the core and the braided sheath. The lubricant coating appears on the surface.

The drawings are diagrammatic and representative. The filaments 11 of the synthetic bioabsorbable suture are at best some what jumbled in actual configuration but are illustrated as patterned in a somewhat idealized style. The coating 12 of the lubricant bioabsorbable polyoxyethylene-polyoxypropylene copolymer is shown much exaggerated. At a level of from 0.1 to 25 percent, the coating would be so thin as to merely be represented by a blurred line if to accurate scale.

In FIG. 2 the core 13 of the braided suture consists of parallel filaments and the sheath 14 consists of a plurality of filaments, typically braided in configuration. The type of braid shown is representative and diagrammatic. The visability and appearance of the coating varies depending upon the observational technique used to inspect the suture.

The coating 12 in part may bridge the gap between the individual filaments in the finished suture. Depending upon the quantity of coating used, the bridging may be more or less complete but complete filling is not necessary. If the coating level is increased, knot run-down continues to be improved, but knot security is compromised.

EXAMPLE 1

Run Down and Chatter Test

A set of 2/0 USP XIX (diameter 0.339 mm, maximum) polyglycolic acid sutures braided from a 2 denier per filament extrusion, was coated with 7 levels of Pluronic F-68 and a blank, that is no coating, then subjected to a square knot run-down test.

In this test, the suture is tied with a square knot around a cylinder with a 4 inch periphery. The loop thus formed is slipped off the cylinder and placed in the testing machine jaws. The knot is subjected to running-down by pulling on the original free ends in a testing machine which records the pull on a chart as the knot travels down the suture. There is some chatter or variation in knot run-down tension as the knot travels down the suture. This is graphically plotted. Out of a set of runs with various coating levels, the fraction is indicated in which the maximum force for the knot run-down is within the separate ranges given in the table. All of the knots for coated sutures ran down the full length of the suture without breaking. The knot breaking strength of the suture braid was in a range of 7 to 8 pounds. For uncoated braid, the knot locked up and the suture broke in 9 out of 10 tests.

TABLE III

Knot Run-Down on 2/0 Polyglycolic Acid Sutures with Pluronic F-68 Lubricant

Coating Level	Fraction of trials where maximum resistance was:						
	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7 lbs.
(percent)							
0.0	broke before run-down in 9 out of 10.						
1.9				2/10	2/10	4/10	2/10
2.8			2/10	3/10	2/10	3/10	
3.9		1/10		1/10	4/10	2/10	2/10
5.0		3/10	2/10	2/10	2/10	1/10	
6.2		2/10	3/10	2/10	3/10		
7.4	3/11	1/11	4/11	3/11			
8.0	5/10	2/10		3/10			
The maximum force for rundown decreases steadily with increasing level. Lower coating levels on a different batch of braid showed							
0.51%	1/10	2/10	2/10	3/10	2/10		
1.09%	5/10	1/10	3/10	1/10			
1.53%	5/10		1/10	1/10	1/10	1/10	1/10

For these coatings, the braid was run through a solution of Pluronic F-68 at a concentration of about twice the percentage of coating on the suture in chloroform.

With other braid constructions and other sizes, the relative ease of knot run-down may be greater or less for the same quantity of coating, or conversely the quantity of the coating may be adjusted to give the desired knot run-down values.

The quantity of the Pluronic in the solvent may be varied, and solvents other than chloroform may be used.

Other organic solvents such as methyl alcohol, ethyl alcohol, isopropyl alcohol, methylene chloride, warm xylene (about 60° C.), tetrahydrofuran, acetone, dimethylformamide, dimethyl sulfoxide, mixtures thereof, and other similar solvents for the lubricant may be used for coating. Flowing the solution onto a moving strand, and letting the surplus drip off is another useful coating technique.

A small amount of water increases the solubility of the lubricants, and aids in coating, but the time of contact with water of the suture should be minimized so that if moisture is present in the coating system, the sutures should be dried and desiccated promptly.

In general it is more convenient to use the solvent coating system at levels below 10 percent pick-up and use a heated die at above about 10 percent pick-up.

EXAMPLE 2

A series of runs was made using a coating of two commercial Pluronics F-68 and F-127 on 2/0 size sutures of 6 dpf braided absorbable polyglycolic acid sutures. The coatings were applied by a solution of the Pluronic in chloroform. The concentration of the Pluronic in the solution used for coating is approximately twice that obtained in the braid. A solution containing about 2.8% Pluronic F-68 in chloroform results in about 1.4% Pluronic F-68 on the braid. An adjustment in concentration can be made to secure any desired level. The strand being coated was braided for a 2/0 size suture using a 6 denier per filament extrusion of polyglycolic acid. An uncoated suture strand of the same lot was used as a control. A standard ATLAB yarn Friction Tester Model CS-151-026, Custom Scientific Instruments, Inc. Whippany, New Jersey 07981, with a Hewlett Packard Model 321 dual channel amplifier recorder was used to record the tension of the strand

feeding into the tester, and coming out of the yarn tester. The chatter factor is the ratio of maximum pull (T_3) to the feed tension (T_1) minus the minimum pull (T_2) to the feed tension, i.e. $(T_3/T_1) - (T_2/T_1)$. The values for friction are of (T_2/T_1) to start slipping.

The values of particular interest are the ratios and percent reduction. With other types of test devices, the numerical values may change, but the relative ratios as an index of improvement are analogous.

In this test, an uncut strand, coated as indicated, was used for the test. For use as a suture, such strand is cut to length, needled, packaged and sterilized using conventional techniques. The friction and chatter is more readily measured on continuous lengths.

Reduction in static friction, chatter and the coefficient of friction are shown for typical coating levels, and sutures in Table IV.

TABLE IV

POLYGLYCOLIC ACID BRAID
Size 2/0

Run No.	Pluronic Coating	Level %	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction $\times 10^{-2}$	% Reduction
1	Blank	0	3.11		0.50		6.109	
2	Blank	0	3.29		0.60		6.2[illegible]4	
3	F-68	1.39	2.78	13.1	0.30	45.5	5.766	7.0
4	F-68	1.93	2.55	20.3	0.19	65.5	5.468	11.8
5	F-68	4.44	2.54	20.6	0.31	43.6	4.900	20.9
6	F-68	7.29	2.70	15.6	0.33	40.0	5.084	17.9
7	F-68	8.09	2.59	19.1	0.25	54.6	5.424	12.5
8	F-127	1.38	2.55	20.3	0.33	40.0	4.938	20.3
9	F-127	1.57	2.63	17.8	0.24	56.4	5.539	10.6
10	F-127	2.56	2.97	7.2	0.27	50.9	6.104	1.50
11	F-127	5.37	2.76	13.8	0.32	41.8	5.689	8.2
12	F-127	5.62	2.82	11.9	0.40	27.3	5.617	9.4
13	F-127	5.62	2.87	10.3	0.29	47.3	6.007	3.1
14	F-127	8.14	2.81	12.2	0.29	47.3	5.891	4.9
15	F-127	9.83	2.74	14.4	0.29	47.3	5.621	9.3

Tests on knot security are dependent on the exact technique of tying knots.

A representative and typical run on knot security showed for a series of tests on size 2/0 polyglycolic acid sutures of 2 denier per filament construction with 4.79% of Pluronic® F-68 coated thereon and different knots, the force in pounds to slip knots or break without slipping to be:

Run	Square Knot	Square + 1 Throw	Square + 2 Throws	Surgeons Knot	Surgeons + 1 Throw	Surgeons + 2 Throws
1	1.70	2.95	Broke	Broke	7.50	Broke
2	2.05	3.90	Broke	6.15	5.15	Broke
3	4.20	4.05	Broke	3.70	Broke	Broke
4	0.70	3.40	Broke	Broke	3.35	Broke
5	3.95	Broke	Broke	1.40	Broke	Broke
Average	2.54	—	—	—	—	—

EXAMPLE 3

A series of runs, including blank, were made with solutions of the Pluronic® R bioabsorbable lubricant copolymers in chloroform, using the procedures of Example II. The following Table V shows the improvement obtained in chatter and friction with a series of polymers and concentrations.

TABLE V

POLYGLYCOLIC ACID BRAID
Pluronic® Size 2/0 - 6 denier per filament

Braid	Run	Coating	Level (%)	Static Friction	(%) Reduction	Chatter Factor	(%) Reduction	Coeff. of Friction $\times 10^{-2}$	(%) Reduction
Uncoated	16			3.92		0.31		8.189	
Uncoated	17			3.45		0.21		7.503	
Uncoated	18			2.87		0.27		6.083	
Uncoated	19			2.87		0.18		6.300	
10297B	20	10R8	2.05	2.51	23.4	0.28		5.077	28
10297B	21	10R8	3.00	2.33	28.9	0.16	34.1	4.932	31
10297B	22	10R8	3.96	2.31	29.5	0.21	13.6	4.753	33
10297B	23	10R8	5.31	2.41	26.5	0.23	5.4	4.962	30
10297B	24	10R8	7.49	2.39	27.1	0.25		4.843	32
10297B	25	25R8	2.55	2.34	28.6	0.16	34.1	4.962	30
10297B	26	25R8	3.85	2.40	26.8	0.15	38.3	5.162	27
10297B	27	25R8	6.29	2.23	32.0	0.15	38.3	4.662	34
10297B	28	25R8	7.15	2.31	29.5	0.13	46.5	4.990	30
10297B	29	25R8	8.74	2.37	27.7	0.11	54.7	5.175	27
10297B	30	31R4	2.18	2.53	22.8	0.15	38.3	5.520	22
10297B	31	31R4	3.42	2.53	22.8	0.17	30.0	5.466	23
10297B	32	31R4	4.51	2.57	21.6	0.14	42.4	5.652	23
10297B	33	31R4	5.53	2.61	20.4	0.17	30.0	5.705	20
10297B	34	31R4	7.26	2.51	23.4	0.11	54.7	5.782	19
10297B	35	17R8	2.12	2.45	25.3	0.19	21.8	5.218	27
10297B	36	17R8	3.13	2.45	25.3	0.25		5.019	30
10297B	37	17R8	5.02	2.33	28.9	0.20	17.7	4.782	33
10297B	38	17R8	6.32	2.36	28.0	0.25		4.723	34
10297B	39	17R8	8.60	2.33	28.9	0.15	38.3	4.962	30

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000102

EXAMPLE IV

A braided polyglycolic acid strand, of a size to form a 2/0 USP suture is dipped in a 10% solution of Pluronic F-68 in chloroform, and dried. The pick-up is about 5% by weight of the weight of the strand itself.

The dried coated strand is cut into 54" segments, needled, packaged, sterilized and dried in accordance with conventional procedures.

The thus prepared sutures were used in surgical procedures. When used to approximate tissue at a wound, a suture is placed in an appropriate location, and tied with a square knot. The square knot readily ran down to pull the edges of the wound to the degree of tightness desired by the using surgeon. The suture shows low tissue drag, and excellent knot run down. When a knot is at a desired final location, three additional squared throws are placed to secure the knot. Knots buried in tissue have the lubricant bioabsorbable copolymer removed from the suture surface within 48 hours, which gives additional knot security. The suture itself maintains tissue retaining strength for at least 15 days, and is substantially absorbed in 90 days.

Whereas exemplified and tested with square knots, the ease of knot run-down and reduced tissue drag are useful in most suture placements and for knot retention. The amount of coating, and the relative values for knot run-down and reduced tissue drag, is variable to suit the requirement of a particular surgical situation.

The needling, packaging and sterilizing of the coated sutures is in accordance with conventional procedures.

We claim:

1. An absorbable surgical suture having improved knot run-down characteristics and reduced tissue drag comprising a polyfilamentary synthetic absorbable polymer strand having thereon a thin lubricating coating of a lubricating absorbable copolymer comprising polyoxyethylene blocks and polyoxypropylene blocks to aid run-down and handleability, said bioabsorbable copolymer having a molecular weight such that it is pasty to solid at 25° C.

2. The suture of claim 1 in which the lubricating bioabsorbable polymer has the formula:

$$R[(CH_2\underset{R_1}{CH}O)_n(CH_2\underset{R_2}{CH}O)_mH]_c$$

where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R.

3. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

$$H(OCH_2CH_2)_x(O\underset{CH_3}{CH}CH_2)_y(OCH_2CH_2)_zOH$$

where x, y and z are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

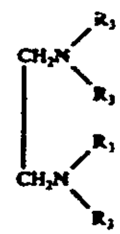
4. The suture of claim 3 in which the lubricating bioabsorbable copolymer has a molecular weight of about 8350 and x and z are about 75 and y about 30, and the melting point is about 52° C.

5. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

$$H(O\underset{CH_3}{CH}CH_2)_n(OCH_2CH_2)_m(O\underset{CH_3}{CH}CH_2)_oOH$$

where n, m and o are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

6. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



where R_3 is

$$—(CH_2\underset{CH_3}{CH}O)_q(CH_2CH_2O)_rH$$

where q and r are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

7. The suture of claim 1 in which the synthetic absorbable polymer strand is of a tissue absorbable polymer subject to hydrolytic degradation to non-toxic tissue compatible absorbable components, and which polymer has glycolic acid ester linkages.

8. The suture of claim 3 in which the synthetic absorbable polymer strand is of a tissue absorbable polymer subject to hydrolytic degradation to non-toxic tissue compatible absorbable components, and which polymer has glycolic acid ester linkages.

9. The suture of claim 4 in which the synthetic absorbable polymer strand is of a tissue absorbable polymer subject to hydrolytic degradation to non-toxic tissue compatible absorbable components, and which polymer has glycolic acid ester linkages.

10. The suture of claim 7 in which the tissue absorbable polymer is polyglycolic acid.

11. The suture of claim 8 in which the tissue absorbable polymer is polyglycolic acid.

12. The suture of claim 9 in which the tissue absorbable polymer is polyglycolic acid.

13. The suture of claim 1 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

14. The suture of claim 2 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

15. The suture of claim 3 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

16. The suture of claim 4 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

17. The suture of claim 7 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

18. The suture of claim 8 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

19. The suture of claim 9 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

20. The suture of claim 10 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

21. The suture of claim 11 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

22. The suture of claim 12 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

23. A method of closing a wound in living tissue which comprises: sewing edges of a wound in living tissue with the sterile absorbable surgical suture of claim 1,

tying the suture into a square knot,

running down the square knot to approximate the tissues in a desired location,

placing additional throws on the square knot, and

within less than about 48 hours bioabsorbing and removing the lubricant absorbable copolymer from the suture thereby increasing knot security and,

leaving the absorbable surgical suture in living tissue until the suture strand is absorbed by living tissue during the healing process, the suture providing useful tissue retention strength for at least 15 days and absorption being substantially complete within 90 days.

* * * * *

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000104

HERMES DECLARATION
EXHIBIT 15 – PART 4 OF 8

United States Patent [19] [11] 4,043,344
Landi et al. [45] Aug. 23, 1977

[54] NON-ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

[75] Inventors: Henry Patrick Landi, Yorktown Heights; Vincent Anthony Perciaccante, Long Island City, both of N.Y.

[73] Assignee: American Cyanamid Company, Stamford, Conn.

[21] Appl. No.: 724,876

[22] Filed: Sept. 20, 1976

[51] Int. Cl.² A61L 17/00
[52] U.S. Cl. .... 128/335.5; 128/1 R; 428/375
[58] Field of Search .... 128/1 R, 335.5; 428/375

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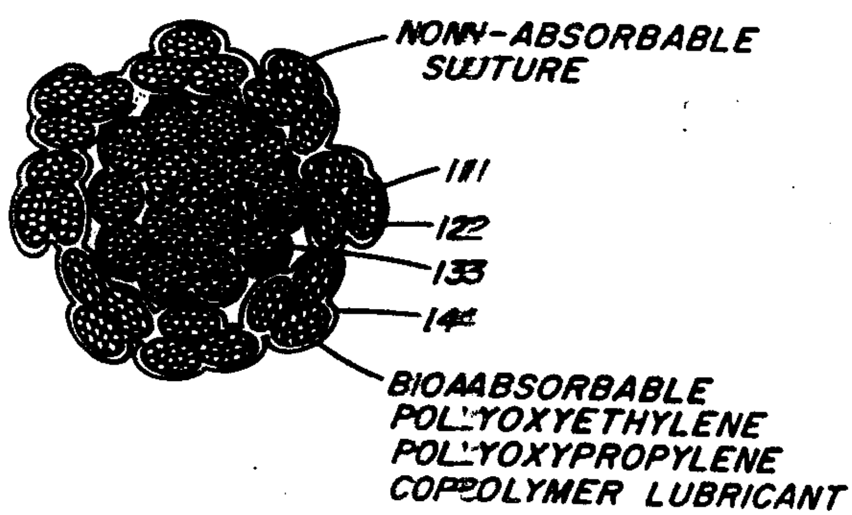
Primary Examiner—Leland A. Sebastian
Attorney, Agent, or Firm—Charles F. Costello, Jr.

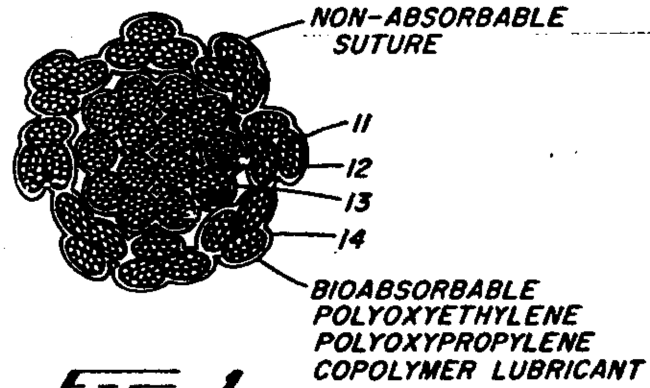
[57] ABSTRACT

The handling characteristics, including particularly the knot run down and tissue drag characteristics, of non-absorbable surgical sutures are improved by a coating of a lubricating film of a bioabsorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks, and which bioabsorbable copolymer has a molecular weight such that it is pasty to solid at 25° C. This lubricant coating is absorbed in tissue in less than about 48 hours—which results in improved long term knot security.

17 Claims, 2 Drawing Figures



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000105


NON-ABSORBABLE SUTURE
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13
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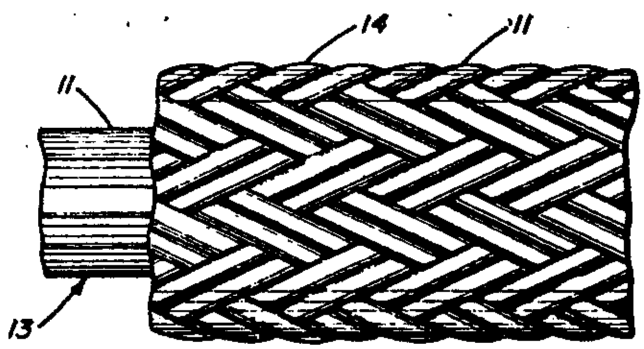
BIOABSORBABLE POLYOXYETHYLENE POLYOXYPROPYLENE COPOLYMER LUBRICANT

FIG. 1


14
11
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13

FIG. 2

NON-ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

BACKGROUND OF THE INVENTION

The handling characteristics of surgical sutures encompass many factors, some of which factors are at least in part inconsistent or seemingly inconsistent. There is a constant effort to improve the handling characteristics. Among the more important of the handling characteristics are those associated with knot rundown. In many surgical procedures it is necessary that a knot be tied in a suture when the knot is deep inside a surgical or natural opening. For instance, a dental surgeon may need to tie a knot inside a patients mouth. An intravaginal hysterectomy requires suturing in restricted quarters. One technique frequently used is to tie a square knot that can be run-down from an exterior location where the knot is first tied to lie against tissue with a desired degree of tightness. The knot is snugged down so that it is holding with a degree of firmness chosen by the surgeon for a particular situation and then additional throws are tied down against the first throws of the square knot. In some instances, the first throw is a double twist followed by a single throw to form a surgeons knot, with additional throws to form additional square knots on top as needed. As contrasted with the ease of placement, is the necessity of knot security. Even though it is desired that it be easy to tie a knot, it is mandatory that the knot hold without slipping for an acceptable length of time.

With buried absorbable sutures, the suture including the knot is absorbed, and the knot need only hold until the suture is absorbed. This can be a few hours for certain types of skin incisions, up to 15 to 28 days for some internal knots.

Non-absorbable sutures are used, if strength for a longer time or permanent reinforcement is desired.

Some suture materials are so smooth that a knot run downs very readily and frequently becomes readily untied. Other sutures are of materials in which the knot tends to "lock-up" or refuse to run-down so that it is difficult to snug-down the throws against the tissue and only a few throws are needed, and security is not a problem. Knots in constantly moving tissue, such as adjacent to the heart, particularly if a non-absorbable suture, have a much greater chance of becoming untied than knots in quiescent tissue such as knots holding together a wound inside a plaster cast.

For knots in non-absorbable sutures which are buried in tissue, the problem of knot security for years has been a problem.

PRIOR ART

U.S. Pat. No. 1,254,031 — Jan. 22, 1918, Davis, SUTURE AND METHOD OF MAKING THE SAME, shows a braided collagen suture immersed in collagen or glue to cause close adhesion of the braid, to fill up the interstices and provide a smooth uniform coating.

U.S. Pat. No. 2,576,576 — Nov. 27, 1951, Cresswell and Johnstone, LUBRICATED THREAD, shows a lubricated multifilament collagen thread using as a lubricating film a phosphatide such as lecithin. The lecithin should be applied at the time of coagulation or regeneration of collagen as effective lubrication is not obtained if the lubricant is incorporated by adding to a finished thread.

U.S. Pat. No. 2,734,506 — Feb. 14, 1956 — Nichols et al. SILK SUTURES AND LIGATURES shows using poly(alkyl) methacrylate as a coating for silk sutures, and a hot coating die system.

U.S. Pat. No. 3,187,752 — June 8, 1956 — Glick, NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING, shows silk or other non-absorbable synthetic filaments such as nylon, cotton or linen coated with a silicone which gives a more inert suture and reduces capillarity.

U.S. Pat. No. 3,209,589 — Oct. 5, 1965 — Schlatter, YARN FRICTION MEASURING INSTRUMENT, describes a machine for measuring the friction of a yarn sliding over itself and describes the variation of friction with speed, and the "slip-stick" variety at slow speeds.

U.S. Pat. No. 3,297,033 — Jan. 10, 1967 — Schmitt and Polistina, SURGICAL SUTURES, shows synthetic surgical sutures of polyglycolic acid and discloses that the surfaces of the fiber can be coated with a silicone, beeswax, or the like to modify the handling or the absorption rate.

U.S. Pat. No. 3,390,681 — July 2, 1968, Kurtz, POLYESTER SUTURE HAVING IMPROVED KNOTTING CHARACTERISTICS, shows improving the knotting characteristics of a polyester such as one formed from a dicarboxylic acid and a diol (Dacron) by depositing on the fibers a polytetrafluoroethylene (Teflon). This patent discloses many of the problems in suture knots, and is hereby incorporated by this reference thereto. This patent also shows the accepted practice of classing "ligatures" under "sutures" for patent disclosure purposes.

U.S. Pat. No. 3,565,077 — Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME, shows a suture construction using polyglycolic acid filaments with a compacted structure and a reduced void fraction.

U.S. Pat. No. 3,815,315, June 11, 1974, Glick, ETHYLENE OXIDE STERILIZATION OF MOISTURE SENSITIVE SURGICAL ELEMENTS shows the desirability of maintaining surgical elements of polymers subject to the hydrolytic degradation to non-toxic, tissue-compatible, absorbable components, such as polyglycolic acid sutures, in a desiccated condition in an air tight container impervious to moisture vapor. Suitable desiccating cycles and foil containers to give products which are storage stable for years are disclosed.

U.S. Pat. No. 3,867,190 — Feb. 18, 1975, Schmitt and Epstein, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, shows the coating of polyglycolic acid surgical sutures with a copolymer of from 15–85% glycolic acid with 85–15% lactic acid which coating fills the interstices of a multi-filament polyglycolic acid suture. Example 10 discloses the coating as minimizing capillarity, and improving run-down. Thicker coatings increase stiffness. This patent has 38 references to earlier prior art on sutures and methods of making them, and related fields and is incorporated herein by this reference thereto. A divisional of said U.S. Pat. No. 3,867,190 is Ser. No. 489,004, July 16, 1974, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, now U.S. Pat. No. 3,982,543 dated Sept. 28, 1976.

U.S. Pat. No. 3,896,814 — July 29, 1975 — Vivieen and Schwartz, COLLAGEN BASED THREADS, shows a collagen or catgut thread which is flexibilized by having therein water and a hygroscopic agent such as a glycerol or a glycol or a low molecular weight (up to 400 m.w.) liquid polyalkalene oxide, and which may additionally be coated with a lipoid or a silicone for surface lubricity.

U.S. Pat. No. 3,942,532 — Mar. 9, 1976 — Hunterer and Thompson — BRAIDED SUTURE, discloses an adaptation of an INSTRON Universal Testing Instrument using an oscillographic recorder, to use a single throw between two suture strands to measure surface roughness, as an indication of the ease of sliding a single throw knot down the suture into place, there called "tie-down performance." A coating of 0.4 percent to 7 percent of the suture weight of an aliphatic polyester such as a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000–3,000 is recommended.

U.S. Ser. No. 691,749, filed June 1, 1976 — Casey and Epstein — NORMALLY-SOLID BIOABSORBABLE, HYDROLYZABLE, POLYMERIC REACTION PRODUCT, discloses the use of trans-esterification product of poly(1,4-propylene diglycolate) and polyglycolic acid and other trans-esterification products of polyglycolic acid and a polyester of diglycolic acid and an unhindered glycol to coat sutures to improve knot run-down and other suture characteristics.

The coating, coloring and conditioning of surgical sutures with polymeric materials in general is well-known. Silicones, wax, polytetrafluoroethylene, and other polymers have been used. Specific coating materials with unique advantages to give improved sutures are constantly being sought.

SUMMARY OF THE INVENTION

It has now been found that the knot run-down characteristics, handleability, tie-down performance and tissue drag characteristics of braided, twisted or covered multifilament non-absorbable sutures may be improved by coating with a lubricating biologically absorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks.

Non-absorbable sutures are sutures which are resistant to biodegradation in living mammalian tissue and remain in the tissue as a foreign body, unless surgically removed (e.g. skin sutures) or extruded. An absorbable suture is degraded in body tissues to soluble products and disappears from the implant site, usually within 2 to 6 months. Non-absorbable sutures retain strength in living mammalian tissue for an extended period, often for the life of the subject. Non-absorbable sutures used for skin closures with the knot above the surface of the skin are removed by the surgeon at a suitable stage of the healing process. For those in which the knot in the non-absorbable suture is buried in living tissue, and are to be left indefinitely, the present lubricant is absorbed from the non-absorbable suture in less than about 48 hours, and hence the lubricating action ceases, and knot security improves.

Non-absorbable sutures are typically of silk, cotton, nylon, a non-absorbable polyester (Dacron ®) polypropylene, polyethylene, or linen. Even metals such as stainless steel, monofilament or braided or tantalum or platinum have been used.

Absorbable or bioabsorbable as applied to the coating, refers to a coating which by hydrolytic or enzymatic degradation, or by its inherent characteristic, has such molecular weight and solubility properties that it is absorbed from the surface of the suture and is eliminated by the subject either unchanged or in hydrolyzed or degraded form.

The lubricant coating not only aids in the knot rundown characteristics but increases the smoothness and flexibility of the sutures so that they may be more easily drawn through the skin and other tissues during placement of the suture. This reduction in friction is called reduced tissue drag. The coating that aids in reduced tissue drag, and lubricates in knot placement also causes the knot to slip more readily.

Another unexpected and unobvious advantage of the present lubricant coating is that the lubricant copolymers are absorbed from the suture within a few days so as the wound heals knot security improves.

The absorbable coating is one or more of a group of compounds having blocks of polyoxyethylene and blocks of polyoxypropylene in their structure. For simplicity and ease of description these compounds are taught, drawn and treated as if there were merely two or three blocks in the chain. However, it is to be understood that non-significant qualities of polyoxypropylene may be present in the polyoxyethylene block and minor quantities of polyoxyethylene may be present in the polyoxypropylene block. From the methods of manufacture it would appear that there may be and probably are such minor admixtures present in the chain. The commercially available grades are acceptable and found to have a low and acceptable degree of toxicity.

The present lubricants may be indicated as having the formula:

$$R[(\underset{R_1}{\underset{|}{CH_2CHO}})_n(\underset{R_2}{\underset{|}{CH_2CHO}})_mH]_c$$

where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R. Those compounds which are at least pasty at 25° C. are preferred because they adhere better to the synthetic absorbable polyfilamentary suture. There is not a sharp cut off, but in general as the materials become more pasty or solid, their effectiveness improves.

The lubricant compound and methods of manufacture are described at length in certain prior art. The Pluronics in general are described in U.S. Pat. No. 2,674,619, Apr. 6, 1954, POLYOXYALKYLENE COMPOUNDS, L. G. Lundsted. These are referred to as a cogeneric mixture of conjugated polyoxypropylene-polyoxyethylene compounds and are further described therein.

Certain nitrogen containing polyoxyethylene detergent compositions which are here useful as lubricants are described in U.S. Pat. No. 2,979,528, Apr. 11, 1961, NITROGEN-CONTAINING POLYOXYALKYLENE DETERGENT COMPOSITIONS, L. G. Lundsted. Column 4, lines 44–58 of this patent disclose that the oxypropylene chains may have a small amount of ethyleneoxide therein and vice versa. Because of the sources of ethylene oxide and propylene oxide, usually

from petroleum fractions, it is to be expected that in commercial practice complete rectification to chemically pure compounds is not obtained. Fortunately the commercial grades may be used on sutures with excellent results. Said U.S. Pat. No. 2,979,528 also points out that as polymers, all molecular species are far from identical—some chains are shorter, some are longer, but on the average the materials are as indicated and it is the physical properties of the lubricants, not the molecular weight spread of the components, which are important.

U.S. Pat. No. 3,036,118, May 22, 1962, MIXTURES OF NOVEL CONJUGATED POLYOXYETHYLENE-POLYOXYPROPYLENE COMPOUNDS, D. R. Jackson and L. G. Lundsted, has much disclosure on the addition of polyoxyethylene groups and polyoxypropylene groups to reactive hydrogen compounds having from 2 to 6 reactive hydrogen atoms and not over 6 carbon atoms per molecule. Among other such compounds are listed the group consisting of aliphatic polyhydric alcohols, alkylamines, alkylene polyamines, cyclicamines, amides, and polycarboxylic acids, oxyethylene groups and oxypropylene groups. The reactive hydrogen compound serves as a chain initiator and can be present in such a small proportion that it has minor significance in its own right and serves mainly as a foundation on which the predominantly polyoxyethylene or polyoxypropylene blocks may be added in the chosen order. Whereas U.S. Pat. No. 3,036,118 claims primarily the Reverse Pluronics in which the polyoxyethylene chains are attached to the nucleus or initiating reactive hydrogen compounds, in the present invention either the Reverse Pluronic with the polyoxyethylene in the center or the regular Pluronics with the polyoxypropylene in the center or the Tetronics with nitrogen in the center may be used for lubricant purposes.

Because the chemistry is previously known, and to avoid unnecessarily extending the length of the present disclosure, the disclosures of each of these three patents is herein hereby incorporated by this reference thereto.

These lubricating bioabsorbable copolymers are often classed as surface active agents as the polyoxyethylene blocks are predominantly hydrophylic and the polyoxypropylene blocks are predominantly hydrophobic. The materials have been sold by the Wyandotte Chemical Company under the trademark of PLURONICS for the formula:

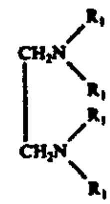
$$H(OCH_2CH_2)_x(\underset{\displaystyle CH_3}{OCHCH_2})_y(OCH_2CH_2)_zOH$$

where x, y and z are whole numbers.

REVERSE PLURONICS for the formula:

$$H(\underset{\displaystyle CH_3}{OCHCH_2})_n(OCH_2CH_2)_m(\underset{\displaystyle CH_3}{OCHCH_2})_oOH,$$

where n, m and o are whole numbers and TETRONICS for the formula:



where R_1 is

$$-(\underset{\displaystyle CH_3}{CH_2CHO})_q(CH_2CH_2O)_rH$$

where q and r are whole numbers.

For the present purposes as lubricants for non-absorbable sutures, the values of x, y, z, n, m, o, q and r are such that the lubricants are pasty to solid at 25° C.

The pastes are opaque semi-solids with melting points above room temperature—preferably above about 40° C.

Those classed as Pluronics are particularly useful for the present invention.

The physical characteristics of these lubricant compounds are affected by their total molecular weight and by the percentage of polyoxyethylene in the molecule. References are made to the commercially available compounds for purposes of convenience. Those which are liquid normally have an L as a primary designator, those which are pasty have a P and those which are solid have an F. For the Pluronics, the first number indicates the typical molecular weight of the polyoxypropylene hydrophobic portion with a number 3 being about 950; 4 being about 1200; 5 being about 1450; 6 about 1750; 7 about 2050; 8 about 2250; 9 about 2750; 10 about 3250; 11 about 3625 and 12 about 4000. The second digit indicates the approximate percentage of the polyoxyethylene hydrophylic units in the total molecular, in units of 10. Thus for example, the formulations of certain commercially available products is approximately that shown in Table I.

As all compositions are mixtures, all values are approximate, and values are subject to some rounding.

Additional data is given in The Journal of the American Medical Association, volume 217, pages 469 to 470 (1971) where the new nonproprietary name of POLOXAMER is established for these compositions as direct food additives.

TABLE I

PLURONIC	Average Molecular Weight	M.W. of each Polyoxyethylene Block	Units of each x and z	% Polyoxyethylene	M.W. of Polyoxypropylene Block	Units of y	M.P. °C.
F-38	5000	2000	46	80	930	16	45
F-68	8350	3300	75	80	1,750	30	52
F-77	6600	2300	52	70	2,050	35	48
P-85	4600	1200	27	50	2,250	39	40
F-87	7700	2700	62	70	2,250	39	49
F-88	10800	4300	97	80	2,250	39	54
F-98	13500	5400	122	80	2,750	47	55
F-108	14400	5600	128	80	3,150	54	57
F-127	12500	4300	98	70	3,900	67	56

TABLE I-continued

REVERSE PLURONIC		M.W. polyethylene units of m block			M.W. polyoxypropylene block	Units of n and O	
10R8	3,000	2000	45	65%	562	9	46
17R8	4,350	2600	59	60%	870	15	53
25R8	9,000	3250	74	57%	1250	22	56

TETRONIC	Average Molecular Weight	Approximate Molecular Weight of Individual Polyoxyethylene Block	Approximate % Polyoxyethylene	Molecular Approximate Weight of Individual Polyoxypropylene Block	Approximate % Polyoxypropylene	Average Approximate length of chains per block Units of r	Units of q
707	12,000	2312	74	673	26	52.5	11
908	26,100	5588	85	923	15	127	15.9
1107	14,500	2438	67	1173	33	55.4	20.2
1307	18,600	3213	69	1423	31	73	24.5
1508	27,000	5063	75	1673	25	115	28.5

In general, the Pluronics with a molecular weight range of from about 4,750 to 16,250 are waxy solids. The polyoxypropylene portion has a molecular weight of 950 to 4,000 and the polyoxyethylene content of about 60–80%.

The pastes in general have a total molecular weight ranging from 3,500 to 5,700 with a polyoxypropylene molecular weight range of 1,750 to 6,500 and polyoxyethylene content of 30 to 50%. The transitions from wax to paste to liquid are not sharp.

COATING

The non-absorbable suture is conveniently coated by several conventional procedures including:

Melt Coating

The uncoated suture is placed in a split die whose orifice corresponds to diameter specifications for the particular size suture to be coated. The die is then clamped in a heating block and the polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer placed in the die. The die is raised to a temperature about 20° C. above the melting point of said copolymer and after the copolymer has melted, the suture to be coated is slowly pulled downward through the molten material in the die and collected on a take-up spool. The spool is mounted directly below the die a sufficient distance to allow solidification of the coated. A cooling tunnel or a blast of cooling air may be used to increase production speeds. Nichols et al. U.S. Pat. No. 2,734,506, supra, describes one useful apparatus for coating.

Solution Coating

The polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer is dissolved in chloroform. About twice the percentage by weight is used for coating solution as is desired on the final sutures. A feed loop such as a loop of wire or a ceramic is threaded with the uncoated suture, after which the feed loop is then submerged in the solution and the suture is passed down through the feed loop. It may be passed through a die whose diameter is such that after drying a suture will have the desired diameter. The suture is pulled slowly through the solution and at least partially dried in a drying tunnel. The drying is finished after the suture is wound on a spool. Because variations in equipment, speed, and temperature affect the pick-up of the lubricant bioabsorbable polymer, the concentration in the coating is adjusted based on a preliminary run or experience.

Other coating techniques which are well known in the coating of polyfilamentary strands may be used. The techniques used for insulating wire may be adapted for large scale suture manufacture. The above are merely two of the more convenient and well known methods for coating. Details are later illustrated in examples.

TOXICITY

The low toxicity of the polyoxyethylene-polyoxypropylene compounds of the present invention are shown in such U.S. Pats. as U.S. Pat. No. 3,450,502 which describes the use of a copolymer having a total molecular weight of about 8,750 in isotonic solutions used as a priming agent in a heart-lung apparatus. In sutures even if a maximum of around 25–30% by weight of the suture of copolymer is used, only a very small amount is placed in the subject.

The low toxicity is shown in the following table.

TABLE II

TOXICITY

Pluronic No.	Total Molecular Weight	Physical Characteristic	LD 50 (gm/kg) in Mice
F-38	5000	wax	>5
F-77	6600	wax	4.2
F-87	7700	wax	3.75
F-6*	8350	wax	>5
F-88	10800	wax	>5
F-127	12500	wax	2.25
F-98	13500	wax	>5
F-108	14400	wax	1.25
P-65	3400	paste	0.83
p-84	4200	paste	0.4
P-85	4600	paste	0.53
P-94	4600	paste	0.6
P-103	4950	paste	1.4
P-104	5850	paste	0.75
P-123	5750	paste	2.7
P-105	6500	paste	3

The polyoxyethylene-polyoxypropylene compositions used as the lubricant bioabsorbable copolymers have been used in food products; and have been the subject of studies as to their elimination from a mammalian body. In general, they are eliminated in the urine fairly rapidly, and within 48 hours nearly all have been eliminated from the blood stream.

If some of the lubricant bioabsorbable copolymer is trapped in braid pores of a suture, the rate of diffusion into the blood stream may be reduced and hence the time for elimination somewhat increased. The molecular weight is small enough that the lubricant bioabsorbable copolymers may be eliminated unchanged, although some degradation may occur before elimination. The important thing is that the lubricant bioabsorbable copolymer has no deleterious effect upon healing tissues adjacent to the sutures, and being removed from the surface of the suture by absorption by the body, knot

security is improved. As soon as suture placement is completed, the knot run down and tissue drag reduction function is complete, and as the lubricant bioabsorbable copolymer is removed from the suture, knot security improves.

Definitions in the suture and textile trades are sometimes ambiguous or confused. As herein used;

A "filament" is a single, long, thin flexible structure of a non-absorbable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a longer continuous thread.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

The term "suture" is used to include the term "ligature" as technically a suture is used with a needle whereas the ligature is merely used to tie without being placed by a needle.

A finished suture has a needle attached and is sterile and ready for use in surgery. For purposes of convenience in nomenclature, the term "suture" is frequently used to refer to the same strand before it is coated and before it is packaged and sterilized. Context indicates whether it is the sterile suture ready for use, or the suture in a manufacturing step which is referred to.

The strand of the suture is used as the basis for weight in determining the quantity of material that is placed on the non-absorbable strand in forming the non-absorbable surgical suture.

The quantity of the lubricating bioabsorbable copolymer is from about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer based on the weight of the uncoated strand forming the suture. It is not necessary that the coating be continuous as a discontinuous coating on the surface aids in reducing friction and chatter. A larger quantity may be present if the lubricating bioabsorbable copolymer penetrates inside the strand, with the various filaments themselves being partially or totally covered.

The wide range of coating weight permits adaptation of the present sutures to many varied uses. Because the strand to be coated to form the suture may have considerable variation in surface roughness, due to the mechanical structure, i.e. braid or twist, etc. as well as being made from filaments which are less than 2 denier per filament to more than 6 denier per filament, with the finer filament sizes giving a smoother surface; and because the filaments may be stretched after the suture is manufactured or in heat treatment, the surface roughness basically can vary. The smoother surfaces require less of the lubricating bioabsorbable copolymer for analogous degrees of slippage.

The various surgical techniques used interact with the desired degree of lubrication. For any given type of knot, a larger quantity of lubricant which for a particular technique increases the ease of run-down, also increases the ease of the knot running back or slipping, called knot security. For some surgical procedures it is highly desirable that the knot be very free in running down, even though the knot slips more readily.

A surgeon in tying knots is confronted with the interaction between the method of tying the knot and the ease of slipping. If a suture is comparatively well lubricated, the surgeon can use a square knot, which is run down readily; with additional squared throws for knot security. On the other hand, if the suture is less well lubricated, the surgeon can use a double half-hitch or some other type of knot which moves more readily to run the knot down to position, after which the double half hitch can be pulled to square the knot, or additional throws can be thrown down against the knot to give adequate knot security. Thus the surgeon can either adapt his knot techniques to a particular suture, or can get sutures whose surface lubricity is best adapted to the technique which the surgeon desires to use. Generally, there is an adaptation of each to the other. The surgeon attempts to get a suture whose characteristics are those which he prefers, and then adapts his knot tying techniques to the sutures that he has at the time. Some surgeons make very successful knots with stainless steel wire using a knotting technique that is adapted to such a wire which has very poor run-down. Others prefer a much more readily run-down well-lubricated suture.

Additionally the location of use has influences. Sometimes a suture in passing through tissue picks up tissue fluids. The suture may be coated with tissue fluids which are either fresh or partly dry at the time the knot is tied. In some surgical techniques it is necessary to preplace the sutures, and tie the suture after the coating of tissue fluids on the suture has a chance to become at least partially dried.

Because the ease of knot run-down and knot security are somewhat opposite, it is necessary for the surgeon to use additional throws or such knots as will hold under the particular conditions of a selected surgical procedure. By changing the quantity of the lubricant bioabsorbable copolymer, the run-down can be modified to suit a using surgeons preference.

The time of use of the knots can be quite varied. Some surgeons use a suture to ligate bleeders in a wound with a retention requirement of 30 minutes or less. Such knots can be removed as the surgical procedure is complete, and before wound closure. Others leave the knots in the tissue even though there is no likelihood that a bleeder would reopen.

Because the present lubricating bioabsorbable copolymer is removed from the suture in living tissue, as the lubricant is removed the knot security increases and after 48 hours more or less, knot security is greatly improved.

The examples following should show the effects of certain different coating and quantities under certain conditions.

The requirements of surgery are extremely varied, and various coating weights permit adaptation of non-absorbable sutures to different conditions.

In general, if the surgeon desires a better lubricated suture, a larger quantity of the lubricating bioabsorbable copolymer is used and conversely if the surgeon is willing to accept slightly reduced knot run-down and tissue drag characteristics in favor of greater knot security, the coating level is reduced in favor of this particular compromise.

Usually from 2 percent to 8 percent of the lubricant bioabsorbable copolymer gives a useful range of compromise between the ease of knot run-down and knot security.

A usage of about 5 percent by weight of Pluronic F-68 is a preferred compromise between the knot run-down and knot security requirements for 2 to 6 denier per filament braided sutures of polyglycolic acid.

In the Drawings:

FIG. 1 is cross-section of a non-absorbable suture having on the surface thereof a bioabsorbable polyoxyethylene polyoxypropylene copolymer lubricant.

FIG. 2 is a drawing of a suture showing the parallel filaments in the core and the braided sheath. The lubricant coating appears on the surface.

The drawings are diagrammatic and representative. The filaments 11 of the non-absorbable suture are at best some what jumbled in actual configuration but are illustrated as patterned in a somewhat idealized style. The coating 12 of the lubricant bioadsorbable polyoxyethylene-polyoxypropylene copolymer is shown much exaggerated. At a level of from 0.1 to 25 percent, the coating would be so thin as to merely be represented by a blurred line if to accurate scale.

In FIG. 2 the core 13 of the braided suture consists of parallel filaments and the sheath 14 consists of a plurality of filaments, typically braided in configuration. The type of braid shown is representative and diagrammatic. The visability and appearance of the coating varies depending upon the observational technique used to inspect the suture.

The coating 12 in part may bridge the gap between the individual filaments in the finished suture. Depending upon the quantity of coating used, the bridging may be more or less complete but complete filling is not necessary. If the coating level is increased, knot run-down continues to be improved, but knot security is compromised.

EXAMPLE 1

Friction and Chatter Tests

A set of 2/0 USP XIX (diameter 0.339 mm, maximum) braided silk sutures was coated with 5 levels of Pluronic F-68; and 12 levels of Pluronic F-127.

4 Blanks were run with no coating, on braid from the same lot, for comparison, and an average of these 4 used for comparative values.

Also 5 runs were made using a commercial silicone coated silk suture, see U.S. Pat. No. 3,187,752, supra, for comparative purposes.

For these coatings, the braid was run through a solution of the Pluronic in chloroform at a concentration of about twice the percentage desired for the coating on the suture, and air dried.

A standard ATLAB yarn Friction Tester Model CS-152-026, Custom Scientific Instruments, Inc. Whippany, New Jersey 07981, with a Hewlett Packard Model 321 dual channel amplifier recorder was used to record the tension of the strand feeding into the tester, and coming out of the yarn tester. The chatter factor is the ratio of maximum pull (T_3) to the feed tension (T_1) minus the minimum pull (T_2) to the feed tension, i.e.$(T_3/T_1) - (T_2/T_1)$. The values for friction are of $(T_2/(T_1)$ to start slipping.

The values of particular interest are the ratios and percent reduction. With other types of test devices, the numerical values may change, but the relative ratios as an index of improvement are analogous.

In this test, an uncut strand, coated as indicated, was used for the test. For use as a suture, such strand is cut to length, needled, packaged and sterilized using conventional techniques. The friction and chatter is more readily measured on continuous lengths.

Reduction in static friction, chatter and the coefficient of friction are shown in Table III.

TABLE III

			Size 2/0 Silk Braid					
Run No.	Pluronic Coating	Level (%)	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction $\times 10^{-2}$	% Reduction
1	Blank	—	3.15	—	0.46	—	6.300	—
2	Blank	—	3.40	—	0.47	—	6.822	—
3	Blank	—	3.32	—	0.46	—	6.690	—
4	Blank	—	3.78	—	0.93	—	6.666	—
5	Silicone	—	3.75	—	0.66	—	7.203	—
6	Silicone	—	3.60	—	0.63	—	6.930	—
7	Silicone	—	3.63	—	0.74	—	6.756	—
8	Silicone	—	3.63	—	0.63	—	7.015	—
9	Silicone	—	3.56	—	0.89	—	6.156	—
10	F-68	2.46	2.85	16.4	0.13	—	6.370	3.77
11	F-68	3.09	2.46	27.*	0.09	—	5.520	16.6
12	F-68	3.51	2.34	31.4	0.07	—	5.190	21.6
13	F-68	3.51	2.44	28.5	0.08	—	5.466	17.4
14	F-68	4.43	2.49	27.0	0.10	—	5.546	16.2
15	F-127	1.68	2.51	26.4	0.08	77.6	5.652	14.6
16	F-127	1.68	2.41	29.3	0.05	91.4	5.466	17.4
17	F-127	2.57	2.51	26.4	0.06	89.7	5.652	14.6
18	F-127	2.57	2.40	29.6	0.09	84.4	5.329	19.5
19	F-127	4.16	2.33	25.8	0.07	87.9	5.782	12.7
20	F-127	4.16	2.39	29.9	0.05	91.4	5.412	18.2
21	F-127	5.16	2.48	27.3	0.06	89.7	5.626	15.0
22	F-127	5.16	2.38	30.2	0.05	91.4	5.357	19.1
23	F-127	5.95	2.45	28.2	0.10	82.8	5.412	18.2
24	F-127	5.95	2.52	26.1	0.07	87.9	5.705	13.8
25	F-127	5.95	2.43	28.7	0.04	93.1	5.520	16.6
26	F-127	7.72	2.43	28.7	0.08	86.2	5.439	17.8

With other braid constructions and other sizes, the relative ease of knot run-down may be greater or less for the same quantity of coating, or conversely the quantity of the coating may be adjusted to give the desired knot run-down values.

The quantity of the Pluronic in the solvent may be varied, and solvents other than chloroform may be used.

Other organic solvents such as methyl alcohol, ethyl alcohol, isopropyl alcohol, methylene chloride, warm xylene (about 60° C.), tetrahydrofuran, acetone, dimethylformamide, dimethyl sulfoxide, mixtures thereof, and other similar solvents for the lubricant may be used for coating. Flowing the solution onto a moving strand, and letting the surplus drip off is another useful coating technique.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000112

A small amount of water increases the solubility of the lubricants, and aids in coating.

In general it is more convenient to use the solvent coating systems at levels below 10 percent pick-up and use a heated die at above about 10 percent pick-up.

EXAMPLE 2

2/0 Nylon Braided Sutures

Using the procedures described in Example 1, runs were made on nylon braid, sized for a 2/0 suture. The reduction in friction, and chatter factors are shown in Table IV. Both uncoated braids from the same lot, and commercial silicone coated nylon were used for comparison.

The reduction in chatter is particularly outstanding.

TABLE IV

2/0 NYLON BRAID

Pluronic Run No.	Level Coating	Static (%)	% Friction	Chatter Reduction	% Factor	Coeff. of Reduction	% Friction × 10^{-2}	Reduction
1	Blank	—	3.02	—	0.33	—	6.300	—
2	Blank	—	2.89	—	0.53	—	6.205	—
3	Blank	—	3.06	—	0.51	—	5.933	—
4	Silicone	—	2.69	10.0	0.34	26.1	5.466	11.1
5	Silicone	—	2.89	3.34	0.42	8.69	5.762	6.25
6	Silicone	—	3.43	—	0.55	—	6.734	—
7	F-68	2.53	2.24	25.1	0.18	60.9	4.632	24.6
8	F-68	2.53	2.47	17.4	0.23	50.0	5.162	16.0
9	F-68	2.53	2.43	18.7	0.16	65.2	5.218	15.1
10	F-68	4.91	2.41	19.4	0.23	50.0	4.942	19.6
11	F-68	5.60	2.29	23.4	0.18	60.9	4.726	23.1
12	F-68	5.60	2.42	19.1	0.20	56.5	5.077	17.4
13	F-68	5.60	2.46	17.1	0.17	63.0	5.274	14.2
14	F-68	6.09	2.54	15.1	0.22	52.2	5.347	13.0
15	F-127	2.83	2.49	16.7	0.19	58.7	5.302	13.7
16	F-127	3.08	2.32	22.4	0.22	52.2	4.783	22.2
17	F-127	3.36	2.36	21.1	0.17	63.0	4.989	18.8
18	F-127	5.60	2.37	20.7	0.17	63.0	4.989	18.8
19	F-127	5.60	2.36	21.1	0.12	73.9	5.133	16.5
20	F-127	5.60	2.38	20.4	0.13	71.7	5.162	16.0
21	F-127	6.21	2.37	20.7	0.15	67.4	5.077	17.4
22	F-127	6.79	2.45	18.1	0.14	69.6	5.329	13.3
23	F-127	7.57	2.65	11.4	0.28	39.1	5.520	10.2

EXAMPLE 3

2/0 Dacron ®Braid Sutures

Using the procedure of Example 1, runs were made on a polyester braid (Dacron ®) sized for a 2/0 suture. The reduction in friction and chatter factor are shown in Table V.

Both uncoated braid from the same lot and silicone coated braid were used for comparison. An average of the uncoated braid runs was used as a base to show improvement.

TABLE V

2/0 Dacron Braid

Run No.	Pluronic Coating	Level (%)	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction × 10^{-2}	% Reduction
1	Blank	—	2.89	—	0.31	—	6.027	—
2	Blank	—	2.65	—	0.34	—	5.310	—
3	Blank	—	2.54	—	0.28	—	5.189	—
4	Silicone	—	2.14	—	0.19	—	4.263	—
5	Silicone	—	2.20	—	0.17	—	4.478	—
6	Silicone	—	2.40	—	0.27	—	4.800	—
7	F-127	2.39	2.60	3.45	0.33	—	5.216	5.30
8	F-127	5.37	2.47	8.28	0.21	32.3	4.996	9.30
9	F-127	5.12	2.36	12.4	0.21	32.3	4.871	11.6
10	F-68	4.03	2.20	18.3	0.19	38.7	4.269	22.5
11	F-68	4.03	2.28	15.3	0.21	32.3	4.628	16.0
12	F-68	5.04	2.45	9.02	0.19	38.7	5.084	7.70
13	F-68	6.26	2.74	16.8	0.18	41.9	4.580	16.8
14	F-68	6.98	2.52	6.42	0.24	22.6	5.247	4.74
15	F-68	8.59	2.26	16.1	0.14	54.8	4.785	13.1

The data in the example is illustrative. Reductions in frictions and improvement in chatter is obtained on all sizes of sutures. With different materials and constructions the results may vary.

The amount of coating and the ease of run-down can be varied to give results desired by the using surgeons.

For sutures, either absorbable or non-absorbable, in which capillarity is a problem, a coating of a phosphatide, preferably purified lecithin, such as taught by U.S. Pat. No. 2,576,576 may be used to reduce capillarity and friction, with the present coating as an additional friction reductant. Lecithin causes tissue irritation under some conditions, particularly if not pure.

EXAMPLE IV

A braided silk suture strand, of a size to form a 2/0 USP suture, is dipped in a 10% solution of Pluronic F-68 in chloroform, and dried. The pick up is about 5% by weight of the weight of the strand itself.

The dried coated strand is cut into 54 inch segments, needled, packaged, sterilized and dried in accordance with conventional procedures.

The thus prepared silk sutures are used in surgical procedures. When used to approximate tissue at a wound, a suture is placed in an appropriate location, and tied with a square knot. The square knot readily runs down to pull the edges of the wound to the degree of tightness desired by the using surgeon. The suture shows low tissue drag, and excellent knot run down.

When a knot is at a desired final location, three additional squared throws are placed to secure the knot. Knots buried in tissue have the lubricant bioabsorbable

copolymer removed from the suture surface within 48 hours, which gives additional knot security.

When removed from test animals after 48 hours, a square knot, without additional throws shows markedly greater knot security than immediately after placement.

In human tissue, in so far as can be observed, the knot security increases as the bioabsorbable lubricant coating is absorbed in tissue.

Whereas exemplified and tested with square knots, the ease of knot run-down and reduced tissue drag are useful in most suture placements and for knot retention. The amount of coating, and the relative values for knot run-down and reduced tissue drag, is variable to suit the requirement of a particular surgical situation.

The needling, packaging and sterilizing of the coated sutures is in accordance with conventional procedures.

We claim:

1. A non-absorbable surgical suture having improved knot run-down characteristics and reduced tissue drag comprising a polyfilamentary non-absorbable strand having thereon a thin lubricating coating of a lubricating absorbable co-polymer comprising polyoxyethylene blocks and polyoxypropylene blocks to aid run-down and handleability, said bioabsorbable copolymer having a molecular weight such that it is pasty to solid at 25° C.

2. The suture of claim 1 in which the lubricating bioabsorbable polymer has the formula:

$$R[(CH_2\underset{R_1}{\underset{|}{C}}HO)_n(CH_2\underset{R_2}{\underset{|}{C}}HO)_mH]_c$$

where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R.

3. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

$$H(OCH_2CH_2)_x(O\underset{CH_3}{\underset{|}{C}}HCH_2)_y(OCH_2CH_2)_zOH$$

where x, y and z are sufficiently large that the lubricating-bioabsorbable copolymer is pasty to solid at 25° C.

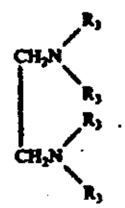
4. The suture of claim 3 in which the lubricating bioabsorbable copolymer has a moelcular weight of about 8350 and x and z are about 75 and y about 30, and the melting point is about 52° C.

5. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

$$H(O\underset{CH_3}{\underset{|}{C}}HCH_2)_n(OCH_2CH_2)_m(O\underset{CH_3}{\underset{|}{C}}HCH_2)_oOH$$

where n, m and o are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

6. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



where R_3 is

$$—(CH_2\underset{CH_3}{\underset{|}{C}}HO)_q(CH_2CH_2O)_rH$$

where q and r are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

7. The suture of claim 1 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

8. The suture of claim 3 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

9. The suture of claim 4 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

10. The suture of claim 1 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

11. The suture of claim 2 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and fricion are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

12. The suture of claim 3 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

13. The suture of claim 4 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

14. The suture of claim 7 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

15. The suture of claim 8 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the

uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

16. The suture of claim 9 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

17. A method of closing a wound in living tissue which comprises: sewing edges of a wound in living tissue with the sterile non-absorbable surgical suture of claim 1,

tying the suture into a square knot,

running down the square knot to approximate the tissues in a desired location,

placing additional throws on the square knot, in a subcutaneous location, and

within less than about 48 hours bioabsorbing and removing the lubricant absorbable coolymer from the suture thereby increasing knot security, and

leaving the non-absorbable surgical suture in living tissue, thereby reinforcing the tissue.

* * * * *

United States Patent [19]

Ohi et al.

[11] Patent Number: 4,946,467

[45] Date of Patent: Aug. 7, 1990

[54] SURGICAL SUTURE

[75] Inventors: Shigeo Ohi; Masakazu Suzuki; Toru Yamamoto, all of Ayabe, Japan

[73] Assignee: Gunze Limited, Ayabe, Japan

[21] Appl. No.: 320,529

[22] Filed: Mar. 8, 1989

[30] Foreign Application Priority Data

Mar. 14, 1988 [JP] Japan .... 63-34397[U]

[51] Int. Cl.⁵ A61B 17/00

[52] U.S. Cl. 606/228

[58] Field of Search 128/335.5; 606/228

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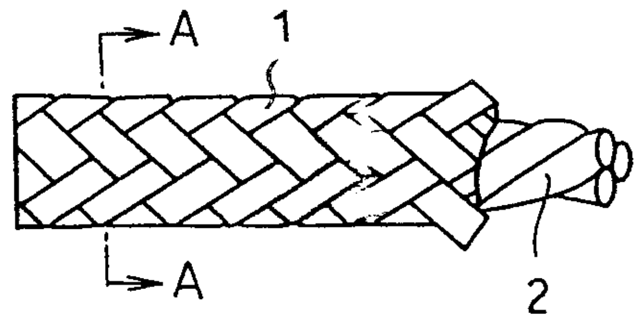
Primary Examiner—Randall L. Green
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Armstrong, Nikaido, Marmelstein, Kubovcik & Murray

[57] ABSTRACT

A suture comprising a core of at least one synthetic fiber filament yarns, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break. The filament yarns have increased modulus of elasticity and increased breaking strength to thereby give the suture improved breaking strength and also have enhanced rigidity to render the suture highly amenable to the correction of its deformation and easier to handle.

10 Claims, 2 Drawing Sheets



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000116

FIG. 1

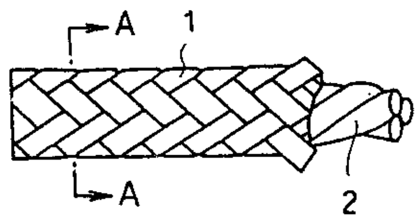


FIG. 2

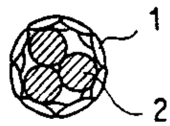


FIG. 3

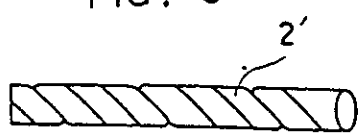
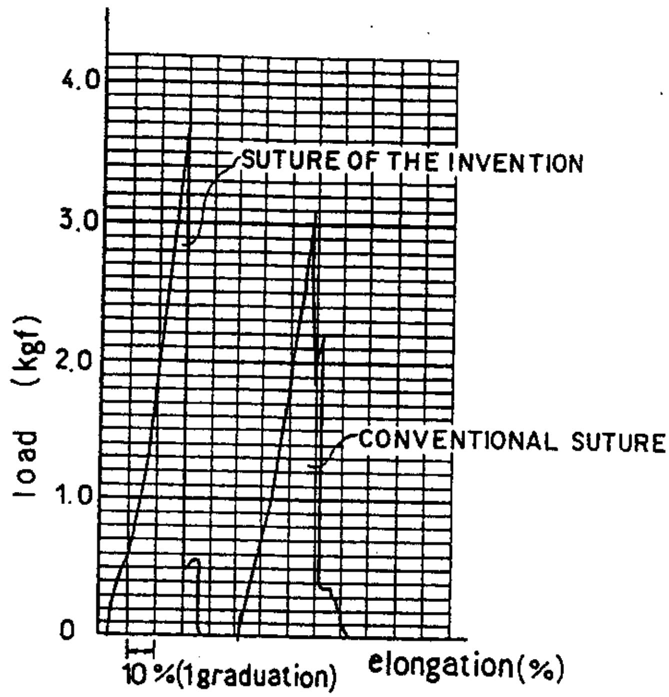


FIG. 4



4.0
3.0
2.0
1.0
0
load (kgf)
SUTURE OF THE INVENTION
CONVENTIONAL SUTURE
10 %(1graduation)
elongation(%)

SURGICAL SUTURE

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention relates to sutures for use in surgery.

2. Description of the Prior Art

Sutures of silk have long been known and used for various surgical applications. Conventional sutures are of various types and include those prepared by twisting, braids formed by plaiting, and braids having a core. The known suture is made of silk only and therefore has the drawback of being low in stiffness and having very poor ability to restore itself when deformed. For example, the suture wound on a reel remains helically curled when unwound therefrom and is difficult to straighten to a corrected form. The same difficulty is also encountered with the suture wound around a paper core.

If the suture used is as curled the suture will coil around the arm or hand of the surgeon or hang down in a helical form due to its excessive flexibility and causes great frustration to the surgeon.

To overcome this problem, we have proposed a suture comprising a core of synthetic fiber filament yarn and a braid or the like of silk strands covering the core (Japanese Utility Model Application No. 41670/1987). The proposed suture is given suitable flexibility due to the appropriate rigidity of the filament yarn as afforded by doubled polyester filament strands in combination with the flexibility of the silk strands covering the yarn, whereby the suture is made amenable to the correction of its deformation such as the curl due to winding so as to be easily handled. Furthermore, the suture has a higher breaking strength than those consisting solely of silk strands owing to the presence of the core of synthetic fiber filament yarn. However, the suture still remains to be improved since there is a demand for sutures having higher strength.

SUMMARY OF THE INVENTION

The main object of the present invention is to provide a surgical suture meeting this demand, and more particularly a suture which has a suitable flexibility and high amenability to the correction of deformation such as the curl due to winding on a reel and is easy to handle and which further has an exceedingly high breaking strength.

To fulfill the above object, the present invention provides a surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break.

The core can be formed of a plurality of synthetic fiber filament yarns extending in parallel to one another and each having substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed of single-twisted or plied filament yarns of synthetic fiber and made to have substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed by plaiting a plurality of synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

The covering layer can be formed by plaiting the plurality of silk strands and made to have substantially the same elongation at break as the core.

The synthetic fiber filament yarn can be made of any of various materials such as nylon, polyester, polypropylene and acrylic, among which polyester which has high breaking strength per denier is especially desirable from the viewpoint of giving improved strength to the suture.

The suture of the present invention has a suitable flexibility due to the rigidity of the core of synthetic fiber filament yarn and because of the flexibility of the covering layer of silk strands, and is thereby given high amenability to the correction of deformation such as the curl due to winding on reels and made easy to handle, hence outstanding advantages. The suture has another advantage; that it is readily deformable to a form suited to suturing during surgery. These great advantages appear attributable also to the fact that slippage occurs more smoothly between the synthetic fiber filament yarn core and the silk strand covering layer than between silk strands.

In the case of the suture already proposed (Japanese Utility Model Application No. 41670/1987) comprising a core of synthetic fiber filament yarn, the filament yarn generally has a higher elongation at break than the silk strands, so that when the suture is stretched under tension, the silk strands reach the limit of elongation (elongation at break) and break first. The force thereafter acts only on the filament yarn to break the yarn. Consequently, the overall breaking strength of the suture is lower than the sum of the individual breaking strengths of the yarn and the silk strands. According to the invention, on the other hand, the core of synthetic fiber filament yarn has substantially the same elongation at break as the covering layer of silk strands, with the result that when the suture breaks under tension, both the core and the covering layer break at the same time. Thus, the sum of the individual breaking strengths of the two is substantially equal to the overall breaking strength of the suture. In this case, synthetic fiber filaments increase in modulus of elasticity as they are made smaller in elongation at break by adjustment through thermal drawing. Accordingly, when the suture comprising such synthetic fiber filaments is compared with the suture comprising usual synthetic fiber filaments, the tensile force acting on the suture when the silk strands are stretched to break is greater on the former suture than on the latter by an amount corresponding to the increase in the modulus of elasticity. Thus, the former suture has a corresponding higher breaking strength. Moreover, the suture has further increased breaking strength because the synthetic fiber filament has higher breaking strength with a decrease in elongation at break. Because of the improved strength, sutures of small diameter are usable for wider application and are advantageous in avoiding injuries to the tissues of the human body to be sutured.

The reduction in the elongation at break gives somewhat increased rigidity to synthetic fiber filaments, makes them more suitable to use and is advantageous in facilitating correction of the deformation of the suture rendering the suture handleable with greater ease.

In the case where the core is formed of synthetic fiber filament yarns extending substantially parallel to one another, it is desirable that the filament yarns be at least 18% to not greater than 24%, more preferably at least 19% to not greater than 21%, in elongation at break

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000119

because silk strands are generally 18to 19% in elongation at break and exhibit an elongation at break of 18 to 24%, usually 19 to 21%, when formed into a covering layer by plaiting and so on.

When the core is prepared from synthetic fiber filament yarns by single twisting, plying or plaiting, the core thus formed is adapted to have the same elongation at break as the covering layer, and the elongation is suitably determined in view of twisting or plaiting density, strength, etc.

When the suture to be obtained has a relatively large size of USP2-0 or greater, it is especially desirable to form the core by plying the yarns so that the first twist and the final twist are in opposite directions to offset the torques due to the twists. For sutures of relatively small size of USP3-0 or smaller, single twisting achieves satisfactory results. Although the number of twists for the core is preferably greater to give improved breaking strength to the suture, the filament yarns may be loosely twisted with about 20 to about 50 T/m when made into a compacted ply.

To assure facilitated correction of deformation and improved breaking strength, it is desirable for the suture to have the core in a greater proportion as will become apparent from the following embodiments, especially from the results given in Table 1.

The present invention will become more apparent from the embodiments to be described below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view partly broken away showing a suture embodying the invention;

FIG. 2 is a view in section taken along the line A—A in FIG. 1;

FIG. 3 is a perspective view showing a core of another embodiment; and

FIG. 4 is a graph showing the relationship between the load and the elongation, as determined for the suture of the invention and a conventional suture and involving a break.

DETAILED DESCRIPTION OF INVENTION

Embodiment 1

Silk strands were each prepared from two scoured silk yarns substantially of 27 denier (median of fineness values involving usual variations) by twisting the yarns together in S direction at about 300 T/m (s27 Naka/2). Silk strands of another type were also prepared each from two silk yarns, the same as those used above, by twisting the yarns together in Z direction at about 300 T/m (z27 Naka/2). A plied yarn serving as a core was prepared by twisting together eight polyester filament yarns (product of Teijin Limited, T300s, 20 denier, composed of 6 filaments, 19% in elongation at break) in S direction at 200 T/m to obtain a twisted unit, and twisting three such twisted units together in Z direction at 137 T/m. The core thus obtained was about 20% in elongation at break. The core was then sheathed with a covering layer by arranging the two types of silk strands alternately on a braiding machine and plaiting the strands, 16 in total number, into a braid at a density of 26 stitches/cm, whereby a suture of USP1-0 in size was obtained. The covering layer formed was about 20% in elongation at break.

The structure of the suture obtained is shown in FIG. 1, in which indicated at 1 is the covering layer formed by plaiting the silk strands, and at 2 is in the core of plied polyester yarn.

The suture prepared in this way had a breaking strength of 2.92 kgf which was 11% higher than that of conventional sutures made of silk yarns only and having the same size. The suture had suitable flexibility (i.e. suitable stiffness), was highly amenable to deformation such as curling and can easily be handled free of trouble. Embodiment 2

A single twist yarn serving as a core 2' as shown in FIG. 3 was prepared from three polyester filament yarns (product of Toray Industries, Inc., S200, 20 denier, composed of 6 filaments, 19% in elongation at break) by twisting the yarns together in S direction at 200 T/m. The core obtained was about 19% in elongation at break. The core 2' was then sheathed with a covering layer which was formed in the same manner as in Embodiment 1 by plaiting twelve silk strands into a braid at a density of 29 stitches/cm, whereby a suture of USP4-0 in size was obtained. The covering layer was about 19% in elongation at break.

The suture thus obtained and having a small size also exhibited excellent characteristics like the suture of Embodiment 1.

Other Embodiments

Sutures of varying sizes were prepared in the same manner as above and tested in comparison with conventional sutures. The results are shown in Table 1, in which the sutures of USP1-0 and USP4-0 in size were made of materials different from those of Embodiments 1 and 2. Accordingly, these sutures were slightly different from the above sutures in the results achieved.

TABLE 1

	USP size	2	1	1-0	2-0	3-0	4-0	5-0	6-0
Invention	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	47	33	33	33	20	20	11	14
	Elongation of break (%)	27.8	25.0	23.7	22.2	20.3	20.0	19.4	18.5
	Breaking strength (kgf)	6.05	3.88	2.92	2.27	1.48	0.95	0.58	0.30
	Flexibility (cm)	18.5	17.5	17.0	17.0	16.0	15.5	12.0	11.0
Prior Art A	Breaking strength (kgf)	5.68	3.76	2.86	2.18	1.41	0.91	0.54	0.28
Prior Art B	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	15	15	15	15	4	4	0	0
	Elongation at break (%)	29.9	27.1	25.2	23.8	22.4	21.8	20.2	19.1
	Breaking strength (kgf)	4.94	3.50	2.79	2.04	1.30	0.83	0.46	0.25
	Flexibility (cm)	16.0	15.0	1.5.5	15.0	14.0	11.5	9.5	8.0

With reference to Table 1, the core ratio is the ratio of the core to the entire suture in weight as expressed in percentage. The flexibility was determined according to the method of JIS L-1096A. Prior Art (prior-art suture)

A was prepared in the same manner as the suture of the invention except that a usual polyester filament yarn (24% in elongation at break) was used as the core. Prior Art (prior-art suture) B had a silk yarn as the core.

The suture of the invention and a conventional suture comprising a core of usual synthetic fiber filament yarn, both USPI in size, were subjected to a tensile test. FIG. 4 is a graph showing the results. The graph reveals that the suture of the invention has exceedingly higher breaking strength (peak value). The graph also shows that with the conventional suture, the descending line representing a break has an intermediate peak, which indicate that the break involves a time lag between the core and the covering layer. With the suture of the invention, the descending line extends downward almost straight, indicating that the core and the covering layer broke at the same time.

When actually used for operations by surgeons, the sutures of the above embodiments were evaluated as being highly amenable to the correction of curls and like deformations, suitably flexible (suitably stiff), easy to handle to assure an efficient operation and free of any break during handling even when of a reduced size.

The suture of the invention is not limited to the foregoing embodiments but can be modified variously within the scope of the invention defined in the appended claims.

We claim:

1. A surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break.

2. A suture as defined in claim 1 wherein the core is formed of a plurality of synthetic fiber filament yarns extending substantially in parallel to one another and each having substantially the same elongation at break as the covering layer.

3. A suture as defined in claim 2 wherein each of the filament yarns is at least 18% to not greater than 24% in elongation at break.

4. A suture as defined in claim 1 wherein the core is formed of a plurality of twisted synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

5. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are single-twisted.

6. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are plied.

7. A suture as defined in claim 5 which is 9—0 to 3—0 in USP size.

8. A suture as defined in claim 6 which is 2—0 to 10 in USP size.

9. A suture as defined in claim 1 wherein the core is formed of a plurality of braided synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

10. A suture as defined in claim 1 wherein the plurality of silk strands are braided to form the covering layer and made to have substantially the same elongation at break as the core.

* * * * *

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(71) Applicant
Fly Fishing Technology Limited

(Incorporated in the United Kingdom)

Units 3/4, Ffrwdgrech Industrial Estate, Brecon, Powys, LD3 8LA, United Kingdom

(72) Inventor
Paul David Burgess

(74) Agent and/or Address for Service
Wynne-Jones Lainé & James
Morgan Arcade Chambers, 33 St. Mary Street, Cardiff, Glamorgan, CF1 2AB, United Kingdom

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester and/or nylon, and the braid may be coated with a sheath of polyurethane.

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"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

SL/SCS

CLAIMS

1. A fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

2. A line as claimed in Claim 1, wherein the other filaments include polyester multi-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monofilaments.

4. A line as claimed in Claim 1, 2 or 3, wherein the braid is coated by a sheath of polyurethane.

5. A line as claimed in any preceding Claim, wherein the polythene is that sold under the Trade Mark DYNEEMA.

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(71) Applicants
Institute für Textil-und Faserforschung Stuttgart, Burgstrasse 29, D—7410 Reutlingen, Germany, Federal Republic of Germany
(72) Inventors
Heinrich Planck,
Wolfgang Joas
(74) Agents
Marks & Clerk,
57/60, Lincoln's Inn Fields, London WC2A 3LS

(54) **Surgical stitching thread**

(57) Surgical stitching thread, has a sheathing (10) in the form of a tubular braided structure, which is braided from a number of multifilament yarns, each of which consists of smooth uncrimped filaments. For reducing the surface roughness of the sheathing the number of bobbins is increased for the braiding process and the number of braids of the sheathing per axial length is reduced.

— A61B 17/04

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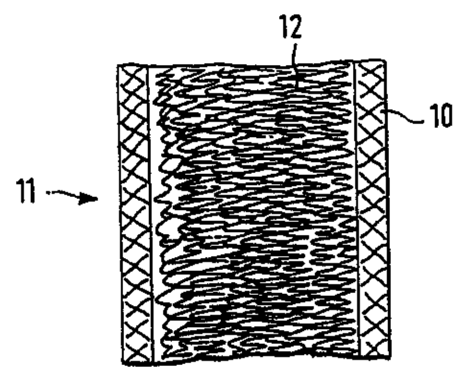
FIG. 2



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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
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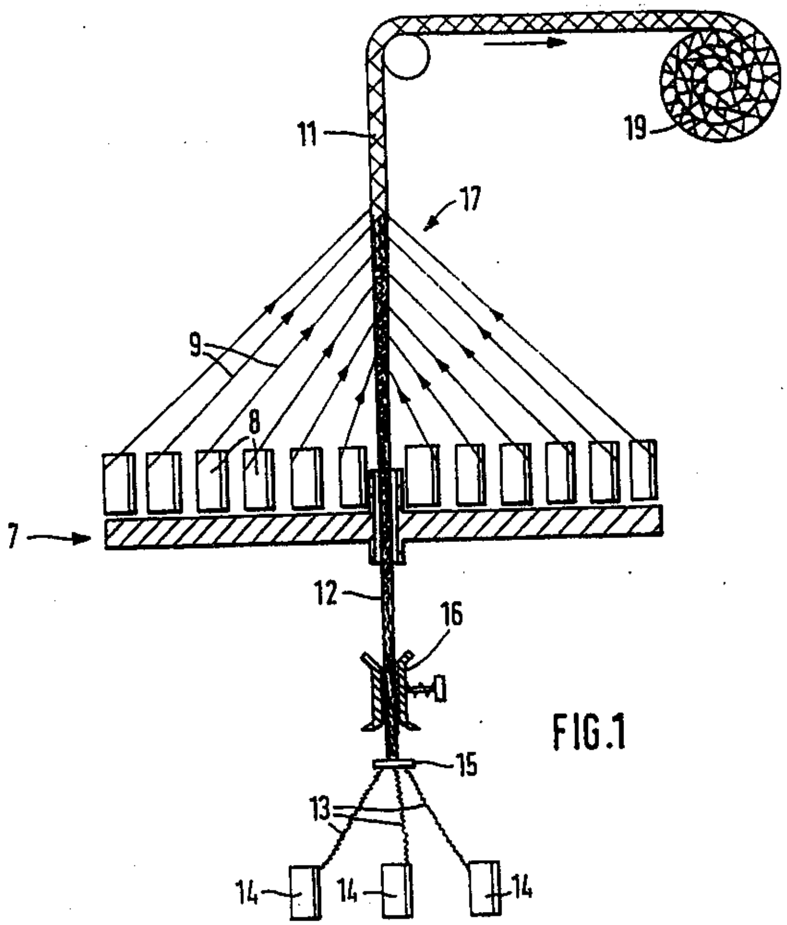

FIG.1

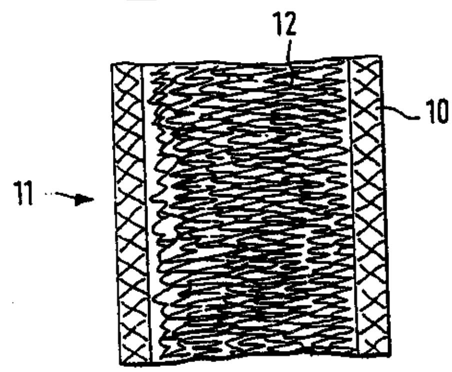

FIG.2

SPECIFICATION
Surgical stitching thread

The invention relates to surgical stitching thread having a tubular braided sheathing composed of a plurality of multi-filaments each of which consists of smooth uncrimped filaments.

Surgical stitching threads of this kind consist of the sheathing alone or of the sheathing and of a core round which this sheathing is wound. The multifilament yarns which are braided together to form the sheathing consists of synthetic plastics filaments which can decompose in the human body (e.g. polyglycolic acid) or synthetic plastics filaments which cannot decompose in the human body (e.g. polyester, polyamide, polypropylene) and/or metal filaments. Filaments of the same materials as for the hitherto known surgical stitching thread can be used for the stitching thread according to the invention. However, filaments from other materials may possibly be considered, in particular materials which are used in the production of synthetic fibres. By "filament" is meant an elongate structure such as can be formed, in the case of synthetic plastics materials, viscose or the like, by means of a hole of a spinning nozzle (spinnaret) or multiple spinning nozzle and, in the case of metal, by means of a hole of a drawing die of a drawing tool. Filaments of synthetic plastics material, viscose or the like are also referred to as endless chemical fibres, elementary fibres or capillaries.

By the hereinafter used term "braid number Z" is meant the number of braids present on a generatrix (also called "edge"), extending axially parallel to the longitudinal axis of the stitching thread, per French inch (equals 27.07 mm).

The following symbols and expressions are used hereinafter:

Z = The number of braids in accordance with the above definition.

K = the number of bobbins (number of bobbins which — in the course of braiding the sheathing — delivered the multi-filament yarns (braiding yarns) which form the multi-filament yarns).

Multifilament yarn = a yarn in the form of a number of filaments.

GT = the count (titre) of the individual yarn, also referred to hereinafter as "individual count", in dtex.

N = the number of yarns of which the core consists.

F = the number of filaments of a multifilament yarn

USP-size = diameter ranges of surgical stitching threads in accordance with United States Pharmacopeiae XIX, pages 486, 665, Pharma Copiae Convention Inc. Meeting at Washington D.C. April 1970, 12601 Twinbrook, USA.

The tubular braided structures of such surgical stitching threads have hitherto been formed with a large number of braids and, in comparison with this a small number of bobbins, and the multifilament yarns which are braided together each had a relatively large individual count (titre); the filaments of the individual yarns also had a relatively large count or titre. Table 1 appended to the end of the specification contains the combinations of values, pertinent to this, of the surgical stitching threads used up to the present time.

Insofar as these known surgical stitching threads had a so-called core, the latter consisted of a ply yarn, which was formed from a number of filament yarns by twisting the latter round one another; the filaments of this ply yarn were uncrimped.

The sheathing forming the outside surface of the surgical stitching thread has relatively high roughness in the case of the numbers of bobbins and numbers of braids which have hitherto been conventional. The result of this, when stitching human or animal tissue by means of these known surgical stitching threads, has been that the stitching threads can cut into the tissue, in the manner of a saw, and thus enlarge the wounds, and delay the healing process. Also, this rough sheathing increases the force required for pulling the surgical stitching thread through the tissue, which makes it more difficult to perform the stitching operation in a sensitive manner.

It is therefore an object of the invention to provide a surgical stitching thread of the type defined at the outset, the outside surface of whose sheathing can be made with lower surface roughness than the surgical stitching threads, made from the same base material, of the same USP size according to Table 1.

According to the invention therefore for the purpose of reducing the surface roughness of the sheathing — the number of bobbins, when braiding the sheathing, in comparison with the known surgical stitching threads, specified in Table 1 of the same diameter range (USP size) is increased, whilst the number of braids of the sheathing in comparison with these known surgical stitching threads is decreased.

To increase the number of bobbins and reduce the number of braids, the outside surface of the surgical stitching thread becomes smoother, that is to say it becomes less rough than is the case with the hitherto conventional stitching threads made from the same basic material and of the same USP size as set forth in Table 1. Consequently, it is possible to pull these surgical stitching threads through human or animal tissue with less force, so that the surgeon can stitch with more sensitivity than hitherto. Also, the human or animal tissue is damaged to a lesser extent by these surgical stitching threads, and so the healing process of the wound is also facilitated.

The individual counts (titres) GT of the yarns of the sheathing of the stitching thread according to

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000128

the invention are, due to the increased number of bobbins, smaller than those of the known stitching threads of the same USP size as set out in Table 1.

The material of the filaments of the sheathing of the surgical stitching thread may consist of the materials which have already been referred to above, preferably of synthetic plastics materials, for example polyester, polypropylene, polyglycolic acid or also of other suitable materials, such as for example viscose silk, natural silk, metal or the like.

The diameter of the surgical stitching threads according to the invention is, in particular, within the range of USP sizes 7—0 to 6. It will be appropriate if the stitching threads are without a core within the USP size range 7—0 and 6—0, and if the stitching threads comprise a core within the size range 4—0 to 6. In the intermediate range of USP sizes 5—0 and 4—0 it will preferably be optional whether the stitching threads contain a core or not.

If the stitching thread according to the invention contains a core, the structure and material of its filaments may be conventional, that is to say these filaments will consist of a ply yarn or of an individual yarn. However, in accordance with a modification of the invention, the core may consist of doubled (folded) multifilament yarns, that is to say these multifilament yarns extend parallel to the longitudinal axis of the stitching thread and are not twisted round one another, that is to say they do not form a ply yarn. Also, in the case of the known surgical stitching threads having a core, the filaments of the core were always uncrimped. This may also be the case with the surgical stitching threads according to the invention. However, in accordance with a modification of the invention, at least some, and preferably all, filaments of the core are crimped, as in this way the surgical stitching thread may be made more pliant, so that its stitching performance and compatibility can be further improved.

Generally speaking, it will be satisfactory if the core consists of one or more multifilament yarns. However, in special cases, the core may consist of a single monofilament or of a number of filaments (viz. monofilaments) which are not twisted round one another, that is to say they are doubled (folded). Conveniently, with a view to ensuring that, in this case, the stitching thread has good qualities of pliability and circularity, the monofilament or monofilaments may consist of elastomeric material, preferably of silicone rubber or elastomeric polyurethane.

Preferred bobbin numbers K and braid numbers Z of the tubular sheathing of the surgical stitching threads according to the invention are specified in claims 2 to 13. The surgical stitching threads specified in claims 14 to 25 result, in practice, in optimally smooth surfaces allied to good qualities of pliability and to other favourable properties of the stitching thread.

The yarns (braiding yarns) used for braiding the sheathing of the surgical stitching thread have, in consequence of the higher bobbin numbers and of the lower braid numbers used for the braiding process, smaller individual counts GT than in the case of the hitherto conventional surgical stitching thread set out in Table 1. Multifilament yarns with the highest possible number of filaments have been found to be particularly favourable for braiding the sheathing of the stitching thread according to the invention.

In *Table 2*, appearing at the end of the specification, preferred structural data are given for a number of surgical stitching threads constituted in accordance with the invention; the numbers K of bobbins and numbers Z of braids in accordance with the preferred embodiments as specified in Claims 14 to 25 appear in this table. The individual counts GT, given in Claims 26 to 29 and in Table 2, of the multifilament yarns forming the sheathings and cores are particularly favourable; similarly, the other structural data given for these surgical stitching threads are also particularly favourable.

Normally, when the sheathing is being formed by braiding, one multifilament yarn runs from each bobbin of the braiding machine concerned to the braiding point. However, it is also possible, in the case of the surgical stitching thread according to the invention — and this may lead to a still more smooth surface of the stitching thread — to arrange for a number of multifilament yarns to run, in doubled (folded) fashion, to the braiding point, from at least one of the bobbins, preferably from all of the bobbins, so that the sheathing will be braided from a correspondingly greater number of multifilament yarns. As has already been mentioned, the multifilament yarns of the sheathing are uncrimped.

Thr smooth outer surface of the surgical stitching thread according to the invention is formed by the outside surface of the sheathing, which has been formed by braiding. Moreover, in special instances, provision may be made for providing the outside surface of the sheathing with preparations or the like for achieving special properties.

Further, it will be feasible in special instances, to replace at least one multifilament yarn of the sheathing by a monofilament or by a number of doubled (folded) filaments, that is to say filaments which abut one another in parallel fashion and are not twisted onto one another.

Embodiments of the invention are illustrated in the drawing, in which:

Figure 1 schematically represents a braiding machine for producing a surgical stitching thread constituted according to the invention, and

Figure 2 is a longitudinal cross-section taken through part of a surgical stitching thread in accordance with one embodiment of the invention; this stitching thread section is represented on a greatly enlarged scale.

The braiding machine 7 shown in Figure 1 comprises twelve bobbins 8, viz. yarn bobbins on which non-crimped multifilament yarns 9 are wound, these yarns 9 being braided so as to form the sheathing

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000129

10 (Figure 2) of a surgical stitching thread 11 to be produced on this braiding machine. The core 12 of this stitching thread, to be formed by braiding, consists of a number of doubled (folded) yarns 13 which, in this embodiment, are crimped multifilament yarns and are drawn off from bobbins 14 and commonly run to a yarn guide 15, pass through a thread brake 16, which is biased in a variable fashion, whence the yarns 13 pass to the braiding point 17, at which they are enveloped by the braiding yarns 9, that is to say the sheathing 10, which envelopes the core 12, are braided from the braiding yarn 9. The production of this surgical stitching thread takes place continuously, and is wound up into a thread package 19.

The short portion, shown in longitudinal cross-section in Figure 2 of an embodiment of a stitching thread 11 according to the invention has a substantially cylindrical sheathing 10 consisting of a tubular braided structure, in the interior of which lies a core 12 which consists of a number of crimped multifilament yarns which extend axially in the sheathing.

The free circumferential surface of this surgical stitching thread is preferably solely constituted by the multifilament yarns of the sheathing. However, it is also possible to provide this sheathing with a finish, which for example has an anti-bacterial action or imparts other desired properties to the stitching thread.

The individual multifilament yarns of the sheathings and cores of the known stitching threads set out in Table 1 have so-called protective twists, that is to say a small degree of twist (e.g. 10 to 130 turns/meter, according to the individual count or titre in each instance). Conveniently, this may also be the case with the surgical stitching thread according to the invention. In accordance with a modification of the invention somewhat better smoothness of the surface of the sheathing can be achieved by making the multifilament yarns of the sheathing twist free, that is to say they have no twist at all. If the core has one or more multifilament yarns, this provision may also be made for these yarns.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000130

TABLE 1

5107	sheathing braided from uncrimped multi-filament yarns			core from non-crimped multi-filament yarns
USP-Size	K	Z	Game	N × GT, f GT in dtex
7–0	4	42 to 53	GT 35, f 15 GT 15, f 10	–
6–0	4 to 6	42 to 50	GT 35, f 15 GT 15, f 10	–
5–0	4 to 8	50 to 80	GT 35, f 15 GT 30, f 20	–
4–0	8	59 to 65	GT 49, f 16 GT 78, f 24	–
3–0	8	56 to 68	GT 95, f 24 GT 76, f 24	1 × GT 150, f 24
2–0	6 to 8	50 to 61	GT 190, f 48 GT 76, f 24	2 × GT 80, f 20 (ply yarn)
0	8 to 12	55 to 60	GT 190, f 48 GT 111, f 32	–
1	12 to 16	53 to 67	GT 190, f 48	1 × GT 226, f 64
			GT 111, f 32	2 × GT 74, f 18 (ply yarn)
2	12 to 16	50 to 67	GT 280, f 72	2 × GT 76, f 18 (ply yarn)
			GT 111, f 32	1 × GT 308, f 108
3 and 4	12	50 to 65	GT 280, f 72	3 × GT 180, f 24 (ply yarn)
			GT 280, f 50	1 × GT 280, f 50
5	12 to 16	52 to 70	GT 380, f 72	5 × GT 180, f 24 (ply yarn)
			GT 340, f 80	3 × GT 455, f 96 (ply yarn)
6	12 to 16	52 to 70	GT 380, f 96	6 × GT 180, f 24 (ply yarn)
			GT 390, f 66	3 × GT 660, f 20 (ply yarn)

TABLE 2

5107	sheathing braided from uncrimped multi-filament yarns				core from doubled (folded), crimped multi-filament yarns		
USP-Size	K	GT (dtex)	f	Z	N	GT (dtex)	f
7—0	8	25	22	8			
6—0	8	25	22	13			
5—0	12	25	22	18			
4—0	12	25	22	20	3	50	24
3—0	12	49	16	18	3	50	24
2—0	16	49	16	23	6	50	24
0	16 or 24	49	16	25	8	50	24
1	18 or 24	49	16	21 or 27	10 or 12	50	24
2	24	49	16	27	12	50	24
3 and 4	20	113	32	25	20	50	24
5	20	113	32	21	30	50	24
6	24	113	32	19	35	50	24
2	18	113	32	21	12	50	24
3 and 4	24	95	24	19	20	50	24
5	24	95	24	19	25	50	24

CLAIMS

1. Surgical stitching thread having a tubular braided sheathing composed of a plurality of multifilament yarns, each of which consists of smooth uncrimped filaments, characterised in that, for reducing the surface roughness of the sheathing, the number of bobbins (K) used for braiding the sheathing is increased in comparison with the known surgical stitching threads, specified in aforesaid Table 1, of the same diameter range (USP-size), and the number of braids (Z) in the sheathing is reduced in comparison with these known surgical stitching threads.

2. Surgical stitching thread of USP-size 7—0 according to claim 1, having its sheathing braided with a number of bobbins K equal to 6, 8 or 10, and with a number of braids Z equal to 8 to 15, in which K is the number of bobbins used for braiding the sheathing and Z is the number of braids per French inch.

3. Surgical stitching thread of USP-size 6—0, according to claim 1, having its sheathing braided with K equal to 8 or 10 and with Z equal to 10 to 20.

4. Surgical stitching thread of USP-size 5—0, according to claim 1, having its sheathing braided with K equal to 10 or 12, and with Z equal to 10 to 20.

5. Surgical stitching thread of USP-size 4—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.

6. Surgical stitching thread of USP-size 3—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.

7. Surgical stitching thread of USP-size 2—0, according to claim 1, having its sheathing braided with K equal to 12, 14 or 16, and with Z equal to 17 to 27.

8. Surgical stitching thread of USP-size 0, according to claim 1, having its sheathing braided with K equal to 14, 16, 18, 20 or 24, and with Z equal to 17 to 27.

9. Surgical stitching thread of USP-size 1, according to claim 1, having its sheathing braided with

K equal to 18, 20 or 24 and with Z equal to 17 to 27.

10. Surgical stitching thread of USP-size 2, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.

11. Surgical stitching thread of USP-size 3 and 4, according to claim 1, having its sheathing braided with K equal to 18, 10, 22, 24, 26 and with Z equal to 17 to 30.

12. Surgical stitching thread of USP-size 5, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.

13. Surgical stitching thread of USP-size 6, according to claim 1, having its sheathing braided with K equal to 20, 22, 24 or 26, and with Z equal to 17 to 30.

14. Surgical stitching thread according to claim 2, having its sheathing braided with K equal to 8, and with Z equal to 8.

15. Surgical stitching thread according to claim 3, having its sheathing braided with K equal to 8 and with Z equal to 13.

16. Surgical stitching thread according to claim 4, having its sheathing braided with K equal to 12 and Z equal to 18.

17. Surgical stitching thread according to claim 5, having its sheathing braided with K equal to 12 and Z equal to 20.

18. Surgical stitching thread according to claim 6, having its sheathing braided with K equal to 12 and with Z equal to 18.

19. Surgical stitching thread according to claim 7, having its sheathing braided with K equal to 16 and with Z equal to 23.

20. Surgical stitching thread according to claim 8, having its sheathing braided with K equal to 16 or 24, and with Z equal to 25.

21. Surgical stitching thread according to claim 9, having its sheathing braided with K equal to 18 or 24, and with Z equal to 21 or 27.

22. Surgical stitching thread according to claim 10, having its sheathing braided with K equal to 24 and with Z equal to 27.

23. Surgical stitching thread according to claim 11, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 27.

24. Surgical stitching thread according to claim 12, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 21.

25. Surgical stitching thread according to claim 13, having its sheathing braided with K equal to 24 and with Z equal to 19.

26. Surgical stitching thread according to any of claims 2 to 5 or 14 to 17, having its sheathing braided from multifilament yarns, each of which has an individual count (titre) of 20 to 30 dtex, preferably of about 25 dtex, and preferably at least 22 filaments.

27. Surgical stitching thread according to any of claims 6 to 10 or 18 to 22, having its sheathing braided from multifilament yarns, each of which has an individual count of 40 to 60 dtex, preferably of about 49 dtex, and preferably at least 16 filaments.

28. Surgical stitching thread according to any of claims 11 to 13 or 23 to 25, having its sheathing braided from multifilament yarns, each of which has an individual count of 80 to 120 dtex, preferably 113 dtex, and preferably at least 32 filaments.

29. Surgical stitching thread according to claim 9 or claim 21, having its sheathing braided from multifilament yarns, each of which has an individual count of 60 to 90 dtex, preferably of about 74 dtex, and preferably at least 24 filaments.

30. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all filaments of its sheathing, made of synthetic plastics material.

31. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all of its filaments, made of metal.

32. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all of its filaments, made of viscose or polyglycolic acid.

33. Surgical stitching thread according to any of the foregoing claims, having at least one filament yarn of its sheathing made of natural silk.

34. Surgical stitching thread according to claim 1, having a USP size of from 7—0 to 3—0, and which exclusively consists of the sheathing.

35. Surgical stitching thread according to claim 1, having a USP size of from 4—0 to 6, and in which a core is arranged within its sheathing.

36. Surgical stitching thread according to claim 35, in which its core comprises at least one multifilament yarn, preferably in the form of synthetic plastics material filaments.

37. Surgical stitching thread according to claim 35, having a core which consists of one or more monofilaments which extend parallel to the longitudinal axis of the surgical stitching thread and are of elastomeric material, preferably silicone-rubber or polyurethane.

38. Surgical stitching thread according to claim 36, having a core which consists of a plurality of multifilament yarns which are braided so as to form a tube.

39. Surgical stitching thread according to claim 36, in which its core consists of a plurality of

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000133

folded (doubled) multifilament yarns.

40. Surgical stitching thread according to any of claims 36 to 39, in which the filaments of its core are uncrimped.

41. Surgical stitching thread according to any of claims 36 to 39, in which at least one filament of its core, and preferably all of its filaments, are crimped.

42. Surgical stitching thread according to any of the foregoing claims, in which the number of multifilament yarns of which the sheathing consists, corresponds to the number K of bobbins used for braiding the sheathing.

43. Surgical stitching thread according to any of claims 1 to 41, wherein the number of multifilament yarns, of which the sheathing consists, is greater than the number K of bobbins used for braiding the sheathing, this being accomplished by arranging that, when the sheathing is being braided, from at least one bobbin at least two multifilament yarns are guided, doubled (folded) and parallel to one another, to the braiding point.

44. Surgical stitching thread according to any of the foregoing claims, and of which its free outer surface is solely constituted by the multifilament yarns of the sheathing.

45. Surgical stitching thread according to any of claims 1 to 25 or 30 to 44, in which a monofilament or a number of doubled (folded) filaments, which are not twisted round one another, replace at least one multifilament yarn of the sheathing.

46. Surgical stitching thread according to any of the foregoing claims, in which the multifilament yarns of the sheathing and/or of the core have a small twist (so-called protective twist).

47. Surgical stitching thread according to any of claims 1 to 45, in which the multifilament yarns of the sheathing and/or of the core are twist free (without twist).

48. Surgical stitching thread composed substantially as hereinbefore described by reference to the accompanying Tables 1 and 2 and the drawing.

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EXHIBIT 15 – PART 5 OF 8

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(72) Erfinder:
Wada, Juro, Prof., Tokyo, JP

(71) Anmelder:
Wada, Juro, Prof.; Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, JP

(74) Vertreter:
Pohlmann, E., Dipl.-Phys.; Schmidt, H., Dipl.-Ing. Dr.-Ing., Pat.-Anw., 8000 München

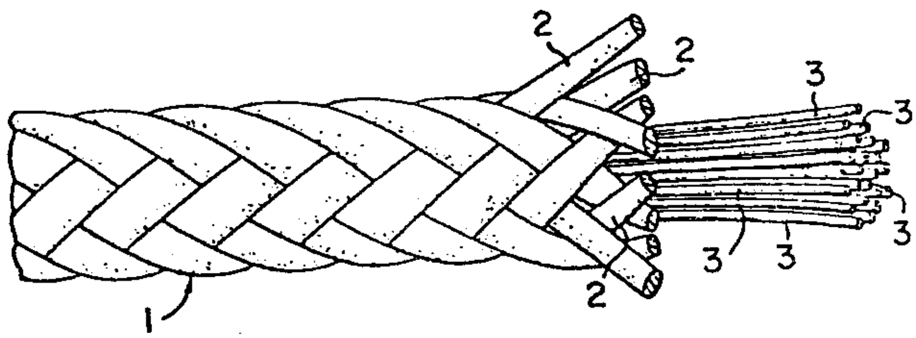
Dr Fritz
Could you provide a translation of summary please

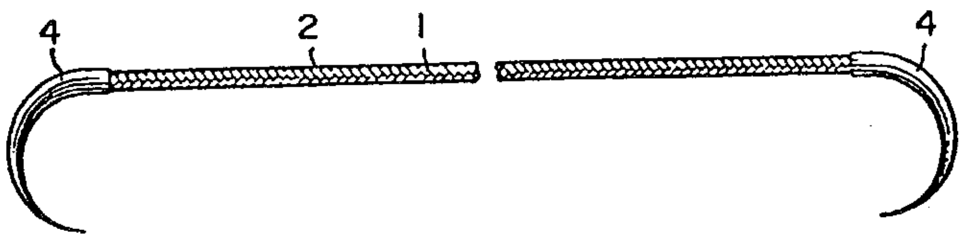
Subject: GERMAN PATENT APPLICATION 29 49 920 AND "MATSUDA MEDICAL"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers (2) surrounding fine platinum fibers or pure gold fibers (3) swaged to at least one surgical needle (4).

2. A surgical suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.





DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
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FIG. 1

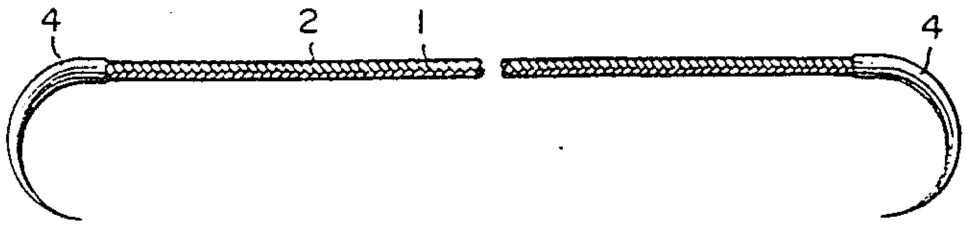


FIG. 2

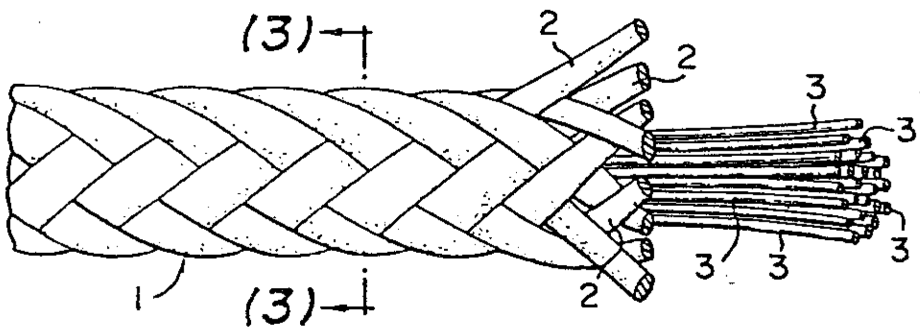
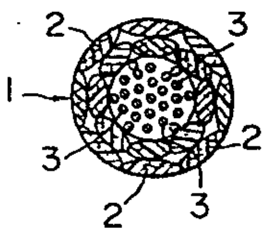


FIG. 3



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Patentanwälte

Dr. Horst Schmidt (Dipl.-Ing.)
Eckhart Pohlmann (Dipl.-Phys.)

Zugelassene Vertreter
beim Europäischen Patentamt

8000 München 40
Siegfriedstrasse 8
Telefon (089) 39 16 39
Telex 5 213 260 pspa d

DE 227/228

Juro Wada, Tokyo, Japan
Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, Japan

Chirurgisches Nahtmaterial

P A T E N T A N S P R Ü C H E

1. Chirurgisches Nahtmaterial, g e k e n n z e i c h n e t durch ein rohrförmiges Geflecht (1) aus sehr dünnen zusammengeflochtenen chemischen Faserfäden (2), durch eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden (3), die in das rohrförmige Geflecht (1) über dessen gesamte Länge eingesetzt sind, und durch wenigstens eine chirurgische Nadel (4), die in einem Stück mit einem Ende des rohrförmigen Geflechts (1) verbunden ist.

- 2 -

T-1213

2. Chirurgisches Nahtmaterial nach Anspruch 1, dadurch gekennzeichnet, dass die sehr dünnen chemischen Faserfäden (2), die das rohrförmige Geflecht (1) bilden, Polytetrafluoräthylen-Faserfäden sind.

T-1213

Beschreibung

Die Erfindung betrifft ein chirurgisches Nahtmaterial.

Als Nahtmaterialien für chirurgische Eingriffe werden bisher in üblicher Weise Materialien aus tierischen Fasern, beispielsweise aus Seide, verwandt. Diese Nahtmaterialien aus tierischen Fasern rufen jedoch eine Reibung mit den inneren Organen bei Bauchoperationen hervor und bringen die Gefahr mit sich, dass die verschiedenen Funktionen der Organe beeinträchtigt werden, was manchmal zu einer Abstossung führt.

Nach der Operation kann darüberhinaus das Nahtmaterial selbst einen Kapillareffekt bewirken. Wenn weiterhin ein künstliches Organ und ein natürliches Organ verbunden werden, besteht die Gefahr, dass das Nahtmaterial selbst mit dem natürlichen Organ verwächst und dessen normale Funktion behindert. Wenn weiterhin eine Infektion auftritt, ist es bisher mit dem Nahtmaterial aus tierischen Fasern unmöglich, die Organfunktion wieder herzustellen, bis das Nahtmaterial entfernt oder körperlich abgestossen ist.

Mit Nahtmaterialien aus Seide oder einem ähnlichen Material war es weiterhin bisher unmöglich, röntgenologisch die miteinander vernähten Teile nach der Operation zu beobachten, so dass es schwierig war, die Funktion des Organs des Körpers nach der Operation zu verfolgen und zu analysieren.

Aufgabe der Erfindung ist daher die Entwicklung eines chirurgischen Nahtmaterials, das die oben beschriebenen Nachteile der bekannten Nahtmaterialien nicht aufweist, d.h. das kein Blut oder andere Körperfluide, Bakterien

- 4 -

usw. überträgt und somit keinen Kapillareffekt zeigt, und das ohne jede besondere Behandlung bei einer chirurgischen Operation einsatzbereit ist.

Diese Aufgabe wird erfindungsgemäss durch ein chirurgisches Nahtmaterial gelöst, das ein rohrförmiges Geflecht aus sehr dünnen zusammengeflochtenen chemischen Faserfäden, eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden, die in das rohrförmige Geflecht über dessen gesamte Länge eingesetzt sind,und wenigstens eine chirurgische Nadel aufweisst, die in einem Stück mit einem Ende des rohrförmigen Geflechts verbunden ist.

Ein besonders bevorzugtes Ausführungsbeispiel des erfindungsgemässen chirurgischen Nahtmaterials zeichnet sich dadurch aus, dass die miteinander vernähten Teile des Körpers nach der Operation röntgenologisch beobachtet werden können, so dass die Funktion des Organs des Körpers nach der Operation verfolgt und analysiert werden kann.

Im folgenden wird anhand der zugehörigen Zeichnung ein bevorzugtes Ausführungsbeispiel der Erfindung näher erläutert:

Fig. 1 zeigt eine teilweise weggebrochene Seitenansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaterials.

Fig. 2 zeigt eine vergrösserte Teilvorderansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaterials, wobei die inneren Metallfäden teilweise durch Abschneiden und Weglassen des äusseren Geflechtes freigelegt sind.

- 5 -

Fig. 3 zeigt eine Schnittansicht längs der Linie 3-3 in Fig. 2.

Wie es in der Zeichnung dargestellt ist, weist das Ausführungsbeispiel des erfindungsgemässen Nahtmaterials ein rohrförmiges Geflecht 1 auf, das aus sehr dünnen zusammengeflochtenen chemischen Faserfäden 2 besteht. Eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden 3 ist in das rohrförmige Geflecht 1 über dessen gesamte Länge eingesetzt. Eine chirurgische Nadel 4 ist in einem Stück mit beiden Enden jeweils oder mit einem Ende des rohrförmigen Geflechtes 1 verbunden, das die Platinfäden oder die reinen Goldfäden 3 umschliesst, die in das Geflecht 1 eingesetzt sind.

Als Faserfäden 2, die das rohrförmige Geflecht 1 bilden, können solche Faserfäden, die eine glatte Oberfläche und eine hohe Dauerhaftigkeit, Abbriebfestigkeit, Biegefestigkeit und Zugfestigkeit haben, beispielsweise Polyfluoräthylen-Faserfäden oder Polyester-Faserfäden, verwandt werden.

Das rohrförmige Geflecht 1 ist dadurch gebildet, dass eine Anzahl von Faserfäden 2 mit einer längenbezogenen Masse von $1/9 \cdot 10^2$ tex zusammengeflochten sind, wobei bei dem in den Fig. 2 und 3 dargestellten Ausführungsbeispiel 16 Fäden verwandt sind.

Die sehr dünnen Platinfäden oder die sehr dünnen reinen Goldfäden 3, die in das rohrförmige Geflecht 1 eingesetzt sind, haben eine Stärke von etwa 50 µm im Durchmesser, wobei etwa 20 derartige Fäden verwandt werden. Diese Platinfäden oder diese reinen Goldfäden 3 haben keinen Einfluss auf die

- 6 -

inneren Organe, wenn sie sich im Körper befinden.

Die chirurgische Nadel 4 besteht aus rostfreiem Stahl oder einem Spezialstahl.

Mit Hilfe des oben beschriebenen Nahtmaterials kann das Ausführen der Naht reibungslos erfolgen, ohne die inneren Organe unnötigerweise zu verletzen, da die Fäden 2, aus denen das Geflecht 1 besteht, glatte Oberflächen haben. Aufgrund der Art seines Materials überträgt das Nahtmaterial darüberhinaus kein Blut oder andere Körperfluide aufgrund des Kapillareffektes. Ohne jede besondere Behandlung des Nahtmaterials können daher ein Anhaften und Fortpflanzen von Bakterien verhindert werden und können selbst dann, wenn Bakterien übertragen werden, die infizierten Bereiche leicht ausgeheilt werden.

Nach dem chirurgischen Eingriff können weiterhin röntgenologische Beobachtungen der Gewebebildung des lebenden Körpers und der Ergebnisse einer Langzeitgewebebildung nach der postoperativen Behandlung, beispielsweise der Nahtbildung, erfolgen und ist es gleichfalls möglich, fortlaufend Änderungen im Zustand des Operationsbereiches mit dessen Wanderung und andere bisher unbekannte Funktionen der Organe des Körpers auf Röntgenfilmen zu beobachten, was für die medizinische Behandlung ausserordentlich nützlich ist.

Das erfindungsgemässe chirurgische Nahtmaterial ist somit am besten für den chirurgischen Einsatz künstlicher Organe geeignet.

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Anmeldetag: 12. Dezember 1979
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FIG. 1

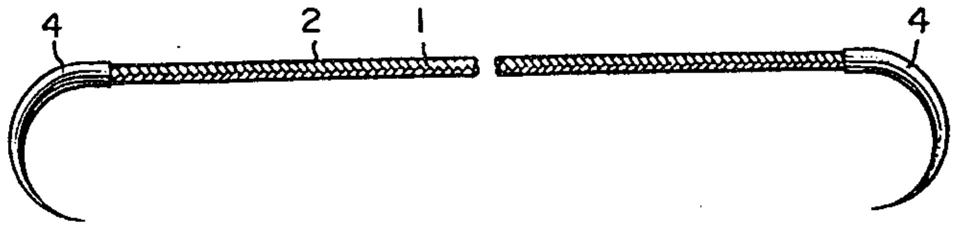


FIG. 2

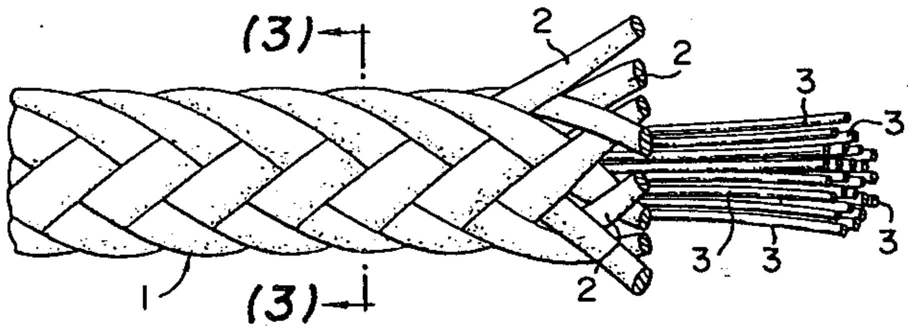
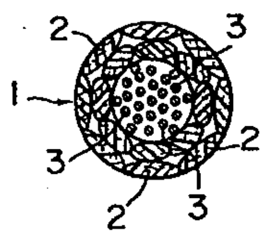


FIG. 3



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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
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Inventor:
Wado, Juro, Prof., Tokyo,JP

Applicant:
Wado, Juro, Prof.; Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, Japan

Representative:
Pohlmann, E.; Schmidt, H.
Patent Attorneys, 8000 Munich

Subject: German Patent Application 29 49 920 and "Matsuda Medical"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers or pure gold fibers (3) swaged to at least one surgiccal needle (4).
2. A surgica suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.

2949920

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DE 227/228

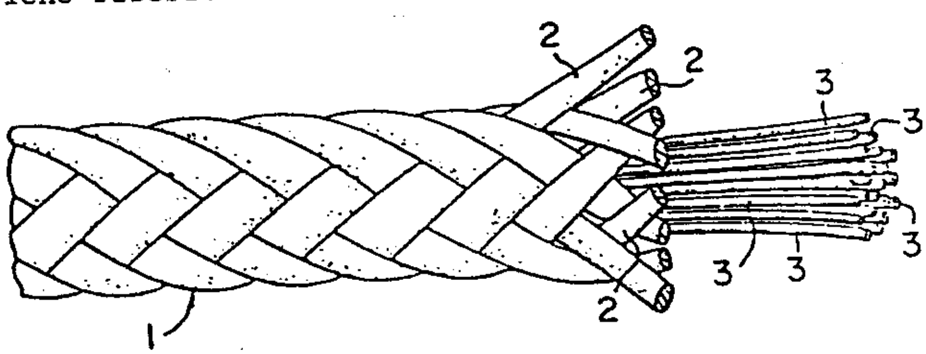
Juro Wada, Tokyo, Japan
Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, Japan

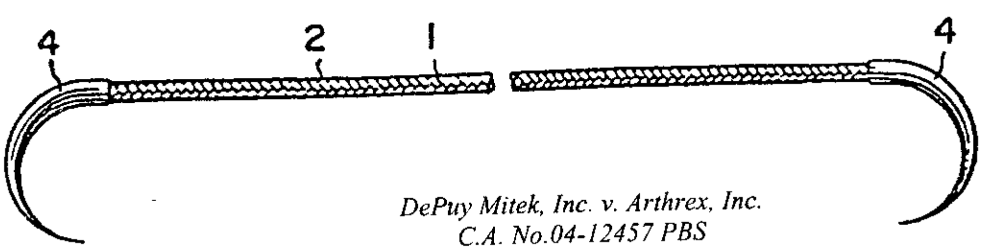
SURGICAL SUTURE MATERIAL

PATENT CLAIMS

1. Surgical suture material characterized by a tubular braid (1) made of very thin synthetic fibers braided together (2), by a number of very thin platinum fibers or pure gold fibers (3) that are inserted into the tubular braid (1) over its entire length, and by at least one surgical needle (4) which is joined integrally to one end of the tubular braid (1).

2. Surgical suture material according to Claim 1, characterized by the fact that the very thin synthetic fibers (2) that form the tubular braid (1) are polytetrafluoroethylene fibers.





Description

The invention relates to a surgical suture material.

Up to now, materials made from animal fibers, for example silk, have commonly been used as suture materials for surgical operations. These suture materials made of animal fibers, however, cause friction with the internal organs during abdominal operations and are accompanied by a danger that the various functions of the organs will be impaired, which sometimes leads to rejection.

In addition, after the operation, the suture material itself can have a capillary effect. Further, when an artificial organ and a natural organ are joined there is a danger that the suture material itself will be overgrown by the natural organ and hinder its normal functioning. Moreover, when an infection occurs, it has up to now been impossible with animal fiber sutures to restore the organ function until the suture material is removed or physically rejected.

Further, with suture materials made of silk or a similar material, radiological observation of the parts sutured together has been impossible after the operation, so that it has been difficult to observe and analyse the functioning of the body organ after the operation.

The objective of the invention is therefore the development of a surgical suture material that does not have the above-described disadvantages of common suture materials, that is, which does not transport any blood or other body fluids, bacteria, etc., and thus does not display any capillary effect, and that is ready for use in a surgical operation without any special treatment.

This objective is achieved according to the invention by a surgical suture material that has a tubular braid made of very thin synthetic fibers braided together, a number of very thin platinum fibers or pure gold fibers which are inserted into the tubular braid over its entire length, and at least one surgical needle that is joined integrally to one end of the tubular braid.

A particularly preferred example of a realization of the surgical suture material of the invention is characterized by the fact that the parts of the body sutured together can be observed radiologically after the operation, so that the functioning of the body organ can be observed and analysed after the operation.

A preferred realization of the invention is described in more detail below with the aid of the accompanying drawings:

Fig. 1 shows a partially cut away lateral view of the realization of the suture material of the invention..

Fig. 2 shows a magnified partial frontal view of the realization of the suture material of the invention, with the inner metal filaments partially exposed by cutting away or omitting the outer braid.

Fig. 3 shows a sectional view along the line 3-3 in Fig. 2.

As is shown in the drawing, the exemplary realization of the suture material of the invention shows a tubular braid 1, which is composed of very thin synthetic fibers braided together. A number of very thin platinum fibers or pure gold fibers 3 are inserted into the tubular braid 1 over its entire length. A surgical needle 4 is joined integrally with both ends or with one end of the tubular braid 1 which surrounds the platinum fibers or the pure gold fibers that are inserted into the braid 1.

As for fibers 2 that form the tubular braid 1, those fibers can be used that have a smooth surface and a high durability, resistance to abrasion, bending strength and tensile strength, for example, polyfluoroethylene fibers or polyester fibers.

The tubular braid 1 is formed by braiding together a number of fibers 2 with a lengthwise mass of $1/9 \times 10^2$ tex, with 16 fibers being used in the exemplary realization shown in Figs 2 and 3.

The very thin platinum fibers or the very thin pure gold fibers 3 that are inserted into the tubular braid 1 have a diameter of about 50 um, with about 20 fibers of this kind being used. These platinum fibers or these pure gold fibers have no effect on the internal organs when they are in the body.

The surgical needle 4 is composed of stainless steel or a special steel.

By means of the above described suture material, the realization of suturing can take place smoothly without injuring the internal organs unnecessarily, since the fibers 2 of which the braid 1 is composed have smooth surfaces. Furthermore, because of the type of material of which it is composed, the suture material does not transport any blood or other body fluid by capillary action. Adhesion and transmission of bacteria can therefore be hindered without any special treatment of the suture material and even when bacteria are transferred the infected region can be healed easily.

Further, after the surgery, it is possible to make radiological observations of tissue formation in the living body and of the result of long-term tissue formation after the post-operative treatment, for example the formation of an anastomosis, and it is likewise possible to observe on x-ray film progressive changes in the state of the area operated on with its migration and other heretofore unknown functions of the body organs, which is extremely useful for the medical treatment.

The surgical suture material of the invention is thus best suited for the surgical implantation of artificial organs.

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(71) Applicant: BIORESEARCH INC. [US/US]; 315 Smith Street, Farmingdale, NY 11735 (US).

(72) Inventors: KURTZ, Leonard, D., Dr. ; 46 Woodmere Boulevard, Woodmere, NY 11598 (US). ARONOFF, Marvin ; 161-18 65th Avenue, Flushing, NY 11365 (US).

(74) Agent: SARRO, Thomas, P.; Larson and Taylor, 727-Twenty-Third Street, South, Arlington, VA 22202 (US).

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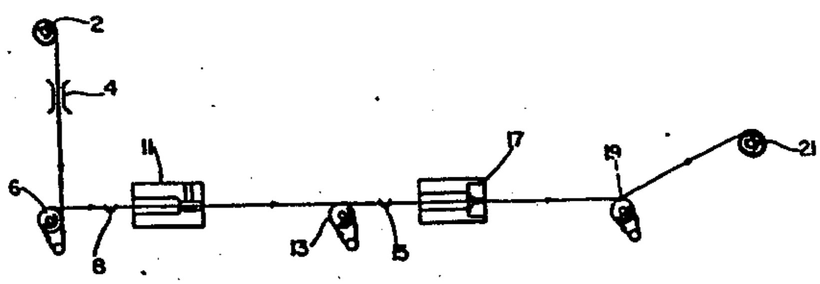
(54) Title: COMPOSITE SURGICAL SUTURES



(57) Abstract

A composite surgical suture of extraordinary high knot strength and capable of use over a range of United States Pharmacopeia (USP) suture sizes is prepared by coating or covering a core of a fiber-forming synthetic polymer material having a knot tenacity of at least 7 grams per denier with a conventional suture material. Illustrative of suitable core materials are, Kevlar, and high strength fully chain-extended crystalline polyethylene.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000150

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COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to improved surgical sutures having extremely high knot strength and to methods for their preparation. More particularly, the invention is directed to composite surgical sutures having a knot strength that enables them to be used over a range of suture sizes classified by the United States Pharmacopeia (USP).

Brief Description of the Prior Art

Surgical sutures are generally divided into two broad classes: (1) absorbable sutures, either natural or synthetic, which are absorbed by the body and (2) non-absorbable sutures, which remain in the body for prolonged periods of time or are removed when the wound heals.

From the patient's viewpoint, whether an absorbable or non-absorbable suture is employed, assuming no toxicity of the suture implant, it is a surgical dictum that the finest suture should be used and that the knot should have the least mass. This dictum is based upon the belief that problems in suture implants are directly related to the size of the suture and the bulk of the mass, i.e., the larger the bulk, the greater the probability of trouble in healing.

Undoubtedly, this was the rational for the original establishment of the USP classification which divides non-absorbable sutures into seventeen sizes: 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7. A few additional

sizes are used which are not USP. Considering that silk was the most widely used non-absorbable suture in the mid-twenties and thirties, this size differentiation was based upon manufacturing. These seventeen sizes could be differentiated one from another by eye. If a finer differentiation were desired, it would not be accomplished becasue of the variation in the raw material as extruded by the silk worm. This classification has been quite useful. Obviously, the number of sizes cannot be considered "standardization" by any means. The sizes are numerous. Unfortunately, it has not been possible to coalesce size because the finer sizes do not have the adequate knot break strength to substitute for the next size.

A further long term problem in surgery is post-operative hernia. It is a truism that scar tissue never achieves the tensile strength of normal tissue. Hernias have occurred many years post-operably through the scar. If a suture were developed which would leave as a residue a non-absorbable suture to support that scar tissue, it would undoubtedly decrease and most likely eliminate the post-operative hernia as a complication.

Composite sutures having a reinforcing core are known in the prior art. None, however, achieve the aforementioned characteristics desired in a suture.

Accordingly, it is an object of the invention to provide a surgical suture with knot strengths so great that suture of much less foreign material is left in the body.

Another object of the invention is to provide a surgical suture having a knot strength that renders it useful over a range of surgical sizes within the USP classification of graded suture sizes, and thus

having the ability to replace the USP graded scale of sizes with just a few finer sutures whose strength would cover the entire range.

A further object of the invention is to provide a composite suture which leaves a residue of non-absorbable suture to support scar tissue and, therefore, decreases or eliminates post-operative hernia as a complication.

Another object of the invention is to provide a method of preparing surgical sutures having extremely high knot strength whose surface characteristics can be tailored to meet desired properties.

A further object of the invention is to provide composite sutures capable of using needles which more closely approximate the outer diameter of the suture.

A further object of the invention is to provide a composite suture having lateral strength, that is, a suture stabilized against abrasion, kinking and/or fibrillation during knotting.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by a sterile, surgical suture having an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier coated with a film and fiber-forming surgical material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

The elongated core of the sutures of the invention can be formed of any fiber-forming synthetic polymer, such as a polyamide, polyolefin, polyester

and the like, having a straight pull tenacity of at least 15 grams/denier, preferably up to 70 or more grams/denier and a knot tenacity of at least 7 grams/denier, preferably up to 30 or more grams/-denier. By "knot tenacity" as used herein and in the appended claims is meant knot break strength divided by the denier. Unless the synthetic polymer making up the suture core of the invention meets the aforementioned knot tenacity properties, the resulting coated core fails to provide a suture which achieves the desired objects of the invention.

Illustrative of synthetic polymer materials suitable for use as the core of the suture of the invention are fiber-forming aromatic polyamides in which the chain extending bonds from each aromatic nucleus are essentially coaxial or parallel and oppositely directed. The term "aromatic nucleus" is used herein to include individual enchained aromatic rings and fused-ring aromatic divalent radicals. The preferred polymers include carbocyclic aromatic polyamides containing up to 2 aromatic rings, including enchained non-fused rings (e.g. 4, 4'-biphenylene) or fused rings (e.g. 1, 5-naphthalene) per amide linkage. The chain-extending bonds from these aromatic rings are para-oriented and/or essentially coaxial or parallel and oppositely directed.

Highly preferred polyamides are characterized by recurring units of the formula:

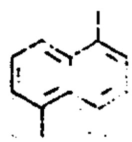
(I) $$\left[\overset{O}{\overset{\|}{C}} - R - \overset{O}{\overset{\|}{C}} - \overset{H}{\overset{|}{N}} - R' - \overset{H}{\overset{|}{N}} \right]$$

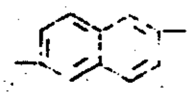
wherein R and R' (when the chain extending bonds are essentially coaxial) are selected from the group of:

 1,4-phenylene, and

 4,4'-biphenylene

and R and R' (when the chain extending bonds are essentially parallel) are selected from the group of:

 1,5-naphthylene, and

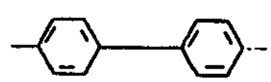
 2, 6-naphthylene

R and R' may be the same or different and may contain substituents on the aromatic nuclei.

Additional highly preferred polyamides of this invention are characterized by recurring units of the formula:

(II) $$\left[\overset{O}{\overset{\|}{C}} - R'' - \overset{H}{\overset{|}{N}} \right]$$

wherein R" is selected from the group of:



Similarly R" may contain substituents on the aromatic nuclei.

As previously stated, the aromatic nuclei of the polymers of this invention may bear substituents. These substituents should be non-reactive during the polymerization and preferably also should be non-reactive (e.g. thermally) during subsequent processing of the polymer, e.g., heat treating of a shaped fiber thereof. Such reactivity is undesirable in that it may cause cross-

linking of the polymer and may adversely effect the dope and/or fiber properties. Among the preferred non-reactive substituents may be names halogens (e.g., methoxy and ethoxy), cyano, acetyl, and nitro. Other suitable substituents non-reactive during the polymerization will be evident to those skilled in the art and are contemplated herein provided such do not adversely affect the desired properties of the dopes and/or fibers of this invention, e.g., due to factors such as steric hindrance. Generally, it is preferred that no more than two (and more preferably no more than one) suitable substituents be present per aromatic nucleus. However, more than two such substituents may suitably be present if the substituent is a relatively small group e.g., methyl.

Both humo-and co-polyamides having substituted or unsubstituted aromatic nuclei, as described above, are well suited for the dopes and fibers of this invention. Random copolymers are preferred copolymers. By the term "random" is meant that the copolymer consists of molecules containing large numbers of units comprised of two or more different types in irregular sequence. The units may be of AB (e.g., from p-aminobenzoyl chloride hydrochloride), AA (e.g., from p-phenylenediamine or 2,6-dichloro-p-phenylene diamine), or BB (e.g., from terephthaloyl or 4,4'-bibenzoyl chloride) type or mixtures of these, provided always that the requirements of stoichiometry for high polymer formation are met. It is not necessary that the relative numbers of the different types of the unit be the same in different molecules or even in different portions of a single molecule.

One or more of these polymers may suitably be

DePuy Mitek, Inc. v. Arthrex, Inc
C.A. No.04-12457 PBS
DMI000157

used in the fibers of this invention, i.e., a single homopolymer; a single copolymer; or homopolymer and/or copolymer blends are suitable herein.

While the polymer chains described above consist essentially of amide links (- CONH -) and aromatic ring nuclei as described above, the polymers useful for preparing the core of this invention may also comprise up to about 10 percent (mole basis) of units not conforming to the above-cited description, e.g., aromatic polyamide-forming units whose chain extending bonds are other than coaxial or parallel and oppositely directed, e.g., they may be metaoriented, or of linkages other than amide, e.g., urea or ester groups.

Among the suitable aromatic polyamides may be named poly(p-benzamide): poly(p-phenylene terephthalamide); poly(2-chloro-p-phenylene terephthalamide); poly(2,6-dichloro-p-phenylene 2,6-naphthalamide); poly(p-phenylene p;p'-biphenyldicarboxamide); poly(p,p'-phenylene benzamide); poly(1,5-naphthylene terephthalamide); ordered aromatic copolyamides such as e.g., copoly(p,p'-diaminobenzanilide terephthalamide), and random copolyamides such as, e.g., copoly(p-benzamide/m-benzamide) (95/5); and many others.

These aromatic polyamides generally have an inherent viscosity and prefereably greater than 1.0. Inherent viscosity (ηinh) defined by the following equation:

$$\eta inh = [\ln (\eta rel)/C]$$

wherein (ηrel) represents the relative viscosity and C represents a concentration of 0.5 gram of the polymer in 100 ml of solvent. Exemplary of such aromatic polyamides are those known as the "Kevlar"

series, products of the DuPont corporation, which generally have a straight pull tenacity of about 18 to 25 grams per denier and a knot tenacity of at least about 7 grams per denier. Further examples of such aromatic polyamides and their methods of preparation can be found, for instance, in U.S. Patent Nos. 3,063,966, 3,600,350, 3,671,542 and 3,819,587 all incorporated herein by reference.

Another example of a synthetic polymer suitable for use as the core of the suture of the invention are high strength polyolefins such as polyethylene which provides fibers having a straight pull tenacity of about 25-50 grams/denier and a knot tenacity of about 7 to 17 grams/denier. These polyolefin fibers are characterized by full chain extension and high crystallization and can be prepared: (1) by ultradrawing of the solidified crystalline polyolefin material that is, by further development of the traditional cold drawing process, and (2) by extending the chains in random state (melt or solution) and inducing them to crystallize in the extended form subsequently. Polyolefins having these characteristics and their method of preparation are described in Keller, A. and Barham, P.J. "High Modulus Fibres", Plastics and Rubber International, February, Volume 6, No. 1 (1981), herein incorporated by reference.

The core of the surgical suture of the invention can be either a monofilament or of multifilament construction. The latter is ordinarily preferred since the coating of suture material subsequently applied generally exhibits stronger adhesion to multifilament cores. The liquified suture material coating tends to penetrate and fill the interstices of a multifilament core as well as

coating the core, thereby anchoring the coating thereto. Multifilament cores can take the form of braids, twisted polyfilaments, yarns and the like.* It should be noted that while the synthetic polymer materials contemplated for use as the core of the composite sutures of the invention, have high axial strength, they are not ordinarily suitable for use as sutures since they do not possess the necessary lateral strength and, therefore, tend to abrade, kink and/or fibrillate during knotting. Coating of the core with a suture material pursuant to the present invention has been found to unexpectedly stabilize, i.e. provide lateral strength resistance against such action thereby rendering suitable for use as sutures these synthetic polymer fibers normally unsuitable for such use.

The surgical suture material used to coat the core can be any film-forming material commonly used in the construction of absorbable and non-absorbable sutures. In general these suture materials when drawn into fibers exhibit straight tensile strengths of about 4 to 10 grams/denier. Examples of the non-absorbable type suture materials are silk (fibroin), polyolefins, such as polyethylene and polypropylene, polyesters such as polyethylene terephthalate and nylon. Examples of absorbable type materials useful as the coating for

* The suture material in the form of multi or monofilament yarn may also be present initially as a core around which the high strength yarn which eventually becomes the core in the finished suture is braided or twisted or it may be formed into a plied, twisted, braided or co-mingled construction with the high strength yarn.

the core include collagen and the synthetic absorbable materials such as polylactide, polyglycolide and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Patent Nos. 3,636,952 and 2,683,136, which patents are herewith incorporated by reference. Such synthetic absorbable polymers are sometimes referred to herein as simply homopolymers and copolymers of lactide and glycolide.

The amount of suture material coated onto the core will vary depending upon the constructon of the core, whether monofilament or multifilament, the number and tightness of braid or twist, the particular tensile strength and knot tenacity of the core, the particular suture material used as the coating and its nature, e.g. melt, solution or solid. In general, when the coating is a non-absorbable suture material, the coating will constitute about 5 to about 10% by weight of the coated core. On the other hand, when the coating is an absorbable suture material, the coating may constitute about 5 to 90% by weight of the coated core.

The coatings can be applied by a variety of suitable techniques well known in the coating art. For example, the coatings can be applied to the core by solution coating, melt coating, extrusion coating and the like.

In melt coating, for example, the uncoated core under tension is slowly passed through a melt of the suture material and then through a die having an orifice smaller than the upper diameter specification for the suture size desired, heated above the melting point of the coating materials, to trim

off excess coating material and shape the composite. Multiple coatings may be applied if necessary.

In solution coating, the suture material is dissolved in a suitable solvent and the core is slowly passed through the coating solution thus formed. The treated core is then passed continuously through a tubular oven heated to an elevated temperature to evaporate the solvent and coalesce and solidify the suture material that remains.

A preferred coating technique when the core being coated is of multifilament construction comprises initially either solution coating or melt coating the multifilament core while the latter is held under a suitable tension and allowing the liquified coating material to penetrate or infiltrate the interstices of the core, thereby forming roots which help anchor the coating of the core. A second layer of the same suture material may then be applied to the impregnated core by any of the conventional coating methods.

In a typical extrusion coating process the core is passed through the cross-head die of a conventional wire coating extrusion apparatus. Pellets of the coating material are introduced into the plastification zone of the extruder wherein they are plasticized into a melt which is forced through the annular die of the extruder and onto the core.

Which coating technique is employed will usually depend upon the particular core utilized. Aromatic polyamide cores, for example, lend themselves to melt or extrusion coating because of their high melting points. The high strength polyethylene cores, on the other hand, have

relatively low melting points, e.g. about 145°C, and must be treated differently. With them, solution coating of the monoor multi-filament cores is the chief method.

According to a preferred embodiment of the invention, when the core being coated is an aromatic polyamide, it is subjected to both a precoating stage and finish coating stage, each of which will be discussed below in more detail.

Impregnation/Precoating Stage

The impregnation/precoating operation of the invention can be conducted using a thread composed of a core made up of multifilaments of a suture material and a plurality of fibers of a synthetic polymer having a tenacity of at least 18 grams/-denier and knot tenacity of at least 7 grams/-denier. The thread can be formed in the usual manner as by twisting, braiding, etc., a plurality of the synthetic polymer fibers around the suture material core. The thread, that is, the covered core is then heated to temperatures above the melting point of the multifilament core material passing it through any suitable oven during which passage the suture material melts and under the tension developed and/or applied exudes upward through the polyfilamentous synthetic polymer component and onto its surface. The amount of coating employed should be sufficient to not only fill all the interstices of the multifilament core component during the melting period but to also coat the surface of the yarn or thread component. Any excess coating material which may have melted out is trimmed off. While the heating of the covered core mixed yarns can be effected with or

without stretching of the thread in some instances, a better final suture is obtained when the yarn is maintained under tension with little or no stretch applied at this stage. It is at this stage that the basic solid coated core structure is developed.

The impregnated and coated core is then passed through a heated dye which trims coating nubs from the core and otherwise smooths the external surface of the thread. Stretch may also be applied during the smoothing operation, but again, best results are obtained with no or minimum stretch. The thread may be passed through the heating oven or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface coating be removed, but some of it should be used to fill the ups and down of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the coating remaining on the surface follows the contours of the thread and any subsequently applied coating will follow these contours.

The temperatures employed in the heating oven will vary depending on the coating employed, the proportions of coating material to core, the speed at which the core is passed through the oven and whether the heating and/or smoothing is conducted under stretch conditions. As aforementioned, the temperature should be raised above the melting point to a level at which the coating material exudes through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which thin the coating material to a point where it runs off should be avoided as they tend to exude too

much coating material and fail to produce a solid case structure.

Generally speaking, when the impregnation/ precoating operation is conducted under stretch conditions, distribution of the coating material throughout the thread and exudation to the surface occurs at lower temperatures than when no stretch is applied. It is important to note, however, that giving the core a high level of stretch in the impregnation/precoating operation reduces or eliminates the ability to apply stretch in the subsequent finish coating stage, in accordance with the preferred embodiment of the invention described below, where it may be used to adjust finished suture properties such as break elongation by additional heat treatment of the highly stretched precoated thread.

The optimum melting temperatures employed in the impregnation/precoating operation will depend primarily upon which suture coating material is employed. The smoothing die temperature will also be above the melting point of the coating material and below the melting point of the core. Usually it will conform closely to the temperature employed in the impregnation/precoating stage preferably about 5 to 15 degrees below that used in the impregnation/precoating stage.

Finish Coating Stage

In the preferred embodiment of the invention, the final stage in obtaining the composite suture structure is to melt extrude coating material onto the smoothed impregnated/precoated thread. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth precoated

thread is simply fed through the extrusion coating die and coated with additional coating material of the same type as used in the impregnation/precoating stage. As aforementioned, it is important to note that the smooth impregnated/precoated thread subjected to the coating stage be essentially free of an undulating surface. The extrusion temperatures employed in the impregnation/precoating stage although it has been found that the higher the extrusion coating temperature, other conditions being equal, the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperature which results in increased polymer flow under a given applied force.

The following examples are included to further illustrate the novel composite sutures of the invention and their preparation. In the examples, reference is made to the following drawings wherein: Fig. 1 is a schematic drawing of an apparatus useful in the impregnation/precoating stage of the present invention; Fig. 2 is a schematic drawing of an apparatus useful in the extrusion coating of the suture impregnated and precoated by use of the apparatus of Fig. 1; and Fig. 3 is a cross-section of the extrusion die in Fig. 2 on a larger scale.

Example I

Directing attention to the drawings, using a conventional New England Butt braider machine 4 strands of "Kevlar", a tradenamed material of DuPont DeNemours, of 30-50 denier having a straight pull tenacity of approximately 7.5 grams per denier are braided around a single core of continuous 40 denier polypropylene having a straight pull tenac-

ity of approximately 4 grams/denier. The raw braid thus formed is wound around a reel 2, and fed through a tensioner 4, about a feed roll (Godet) 6, guide 8 and into a heated 10 cm long tubular oven. The lumen of an extrusion coating die without feed serve this purpose and is designated Heated Zone I in Fig. 1. A draw roll (Godet) 13 pulls the raw braid through the oven without stretch, that is, at a stretch ratio (SR) of 1:1. The Heated Zone I is maintained at a temperature of 230°C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Heated Zone I, large quantities of excess polypropylene which have melted out are trimmed off manually. The braid then continues through a Guide 15 to Heated Zone II which contains a smoothing die 17 having a 0.2 mm diameter that trims and smooths down nubs that are formed on the braid. Heated Zone II is maintained at a temperature of about 220°C for the smoothing operation. The smoothed braid is pulled through Heated Zone II by a draw roll (Godet) 19 and onto receiving reel 21. The speed at which the braid passes through both Heated Zone I and II is approximately 1-1.8 M/min. The precoated braid is passed through the smoothing die 17 three times so as to obtain an impregnated/precoated braid of the desired smoothness.

Referring to Fig. 2, reel 31 of smooth impregnated/precoated braid prepared as above is passed through a tensioner 33, to feed roll (Godet) 35 which feeds the braid through guide 37 into extrusion coating die apparatus indicated generally

as 39. Polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260°C and the melt is forced by means of extruding weights 43 applied at a force of 0.233 kg to a piston 45 into and through the extrusion coating die.

Directing particular attention to Fig. 3, the extruding coating apparatus is comprised of a holder indicated generally as 47 which houses a hollow lumen member 49 a spinneret 57 having an outlet 52. The lumen member 49 essentially positioned within the holder 47 so as to provide an annular chamber 53. A gasket 55 seals one end of the member 49 within the holder while the other end is supported by slotted plate 60. The lumen member contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the spinneret 57 is positioned a hollow needle 63. The impregnated/precoated thread 65 passes consecutively through lumen member 49, hollow needle 59, outlet 52 and is coated with melt as it emerged from the die. The coating die is maintained at a coating temperature of 235°C.

The coated filament is then taken up on draw roll 48 which applies stretch. Tension is let down on draw roll 50 which is run more slowly than draw roll 48. The yarn velocity is 1.43 M/min. and the total stretch ratio (SR) is 1.02. The finished suture is finally wound around receiving reel 51.

The result is a finished composite suture with a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional area and exhibiting a knot break strength of about 3.2 pounds. A knot break strength of 3.2 pounds is equivalent to USP limits of size 2.0 monofilament suture. Thus,

BUREAU OMPI WIPO INTERNATIONAL

the composite suture prepared can be used as a 5/0, 4/0, or 3/0 suture.

Example II

The process of Example I is repeated substituting a polyethylene terephthalate core for polypropylene core and extrusion coating in extrusion coating die apparatus 39 with polyethylene terephthalate. The result is a composite suture having a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional volume coated with polyethylene terephthalate exhibiting a knot break strength of about 3.5 pounds which is a knot brek strength above the USP limits for a 2/0 size suture. Therefore, the composite suture prepared could be used for sizes 5/0, 4/0, 3/0 and 2/0 according to the physician's wishes.

Example III

Fibroin (silk) is dissolved in a aqueous solution of 62% zinc chloride to give a solution having fibroin weight % concentrations in the range of 5-20%. The resulting solution is maintained at approximately its boiling point and "Kevlar" yarn of Example I is pulled through the solution at a constant rate as to fully impregnate and coat the yarn. The impregnated and coated yarn is then dried by passing it through a tubular oven maintained at heating temperatures up to 130°C. The heat treatment evaporates the solvent and helps to form a continuous fibroin film. The composite suture is then washed with cold water to remove residual zinc chloride.

The resulting composite suture with a size 5/0 "Kevlar" core containing approximately 5% by weight fibroin exhibits a knot break strength of approximately 3.5 pounds which is equivalent to a silk

suture of size 2.0. In other words, the silk-coated "Kevlar" composite suture could be used instead of silk in the following sizes: 5/0, 4/0, 3/0 and 2/0.

Example IV

A size 5/0 high strength fully chain-extended polyethylene multifilament yarn having a straight pull tenacity of 50 grams/denier and a knot tenacity of 15 grams/denier is pulled through a 10% solution of polyethylene terephthalate in a solvent mixture of methylene chloride containing 31% by weight hexafluoroisopropanol and then passed through a die to trim off excess solution. The coated core is dried in air and the process repeated to build up the coating to a final composite suture containing 10% by weight polyethylene terephthalate. The composite is washed with water and dried again. The resulting composite suture could be used for sizes 5/0, 4/0, 3/0, 2/0 and 1/0.

Example V

Example I is repeated substituting a polyglycolic acid (PGA) core for the polypropylene core and PGA resin for the polypropylene chips. The resulting "Kevlar"/polyglycolic acid composite has a minimum knot break strength in the range of 1550-1700 grams. Since commercial non-absorbable "Prolene" sutures of size 3/0 has a knot strength of 1550-1650 grams, this means that a size 3/0 "Kevlar"/polyglycolic acid suture will retain the knot break strength of 3/0 "Prolene" after absorption of all the polyglycolic acid. Thus, the "Kevlar"/polyglycolic acid suture prepared could be used for sized 3/0, 4/0 and 5/0.

When 6/0 size "Kevlar" reinforcing core is used with a non-reinforcing PGA coating, the core by

itself will give a knot strength midway between size 4/0 and 5/0 based on "Prolene" knot strength but above the USP standards for 4/0. Thus, PGA coated "Kevlar" composites with a 6/0 core could be used for size 6/0, 5/0 and possible size 4/0.

With size 7/0 reinforcing core and PGA non-supportive coating 6/0 strength is obtained. Thus, PGA coated, 7/0 core "Kevlar" can be used for sizes 6/0 and 7/0.

Using high strength, extended chain polyethylene having 50 gram/denier straight breaking tenacity, with approximately 1/3 of this converting to knot tenacity, a 5/0 size reinforcing high strength polyethylene core of about 0.140 mm in diameter will impart at least the knot strength of a 2/0 suture to the composite. Thus, a PGA-coated high strength polyethylene 5/0 core can be used to make sizes 2/0, 3/0, 4/0 and 5/0 absorbable, non-absorbable composite sutures.

With high strength polyethylene 6/0 size reinforcing core of about 0.90 mm diameter and a non-supporting PGA coating, the core itself will provide enough knot strength for sizes 4/0, 5/0 and 6/0 based on the knot strength of "Prolene".

With high strength polyethylene 7/0 size reinforcing core of about .060 - .065 mm in diameter and non-reinforcing PGA coating, the core itself will give knot strength sufficient for 5/0, 6/0 and 7/0 composites based on the knot strengths of "Prolene".

With higher strength materials or by increasing the knot strength of the materials mentioned here, a wider spectrum of sizes could be covered with the same fine sized reinforcing core.

In commercial production, needles may be

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attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time without a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

Another advantage offered by the composite sutures of the invention is that needles of smaller diameter can be attached thereto. In accordance with this feature of the invention the outside cover or coating of suture material at the end of the composite suture is removed by any suitable means as, for instance, by dissolving the cover using a solvent which solubilizes the cover but not the core. The core at the end of the suture is thereby exposed and onto the core is attached as, for instance, by swagging a needle of smaller outer diamter than would be used with a suture of the same outer diameter. The following example illustrates this feature of applicants' invention:

Example VI

The end of a composite suture prepared according to the general procedure of Example I and having an outer diameter of approximately 0.012 inch is dipped one-eighth inch into boilin xylene until the polypropylene cover softens. The polypropylene cover is then manually scrapped off to expose the 5/0 "Kevlar" core. A 0.014 inch diameter needle is swagged onto the core to provide a suture with a needle having a cross-sectional area reduced approximately two-thirds that of needles required for sutures having a 0.012 inch diameter.

IT IS CLAIMED:

1. A sterile, surgical suture comprising an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams per denier coated with a filmand fiber-forming surgical suture material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

2. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is an aromatic polyamide.

3. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

4. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(1,4-benzamide).

5. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

6. A sterile, surgical suture according to claim 1 wherein the surgical suture material is fibroin.

7. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyester.

8. A sterile, surgical suture according to claim 1 wherein the polyester is polyethylene terephthalate.

9. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyolefin having a straight pull tenacity of about

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21. A sterile, surgical suture according to claim 2 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided construction.

22. A sterile, surgical suture according to claim 20 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

23. A sterile, surgical suture according to claim 1 wherein the coating of film-forming suture material comprises 5 to 10% by weight of the suture.

24. A sterile, surgical suture according to claim 13 wherein the coating of film-forming suture material comprises 5 to 90% by weight of the suture.

25. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier, with a fiberand film-forming surgical suture material, said coated core when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

26. A method according to claim 25 wherein said coating is effected by solution coating.

27. A method according to claim 25 wherein said coating is effected by melting coating.

28. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers

4 to 10 grams/denier.

10. A sterile, surgical suture according to claim 1 wherein the polyolefin is polyehtylene.

11. A sterile, surgical suture according to claim 1 wherein the polyolefin is polypropylene.

12. A sterile, surgical suture according to claim 1 wherein the surgical suture material is collagen.

13. A sterile, surgical suture according to claim 1 wherein the surgical suture material is a film-forming absorbable synthetic polymer.

14. A sterile, surgical suture according to claim 13 wherein the absorbable synthetic polymer is selected from the group consisting of film-forming homopolymers and copolymers of lactide and glycolide.

15. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of glycolide.

16. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of lactide.

17. A sterile, surgical suture according to claim 1 wherein the core is in monofilament construction.

18. A sterile, surgical suture according to claim 2 wherein the core is in monofilament construction.

19. A sterile, surgical suture according to claim 18 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

20. A sterile, surgical suture according to claim 1 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided constructon.

of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, then smoothing said coating.

29. A method according to claim 28 wherein said smoothing is effected by passing said heated thread through a heated smoothing die.

30. A method according to claim 28 wherein the surgical suture material is selected from polyolefin and polyester.

31. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a straight pull tensile strength of at least 18 grams/denier and a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, smoothing said coating and melt extruding similar surgical suture material onto said smoothed coating.

32. A method according to claim 31 whrein the surgical suture material is selected from polyolefin and polyester.

33. A method according to claim 25 wherein the coating is effected by solution coating.

34. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of synthetic polymer having a knot tenacity of at least 7 grams/denier and a lateral strength insufficient to prevent abrasion, fibrillation or kinking on knotting with a film and fiber-forming surgical material in an amount sufficient to increase the lateral strength of said core and provide resistance against said abrasion, fibrillation or kinking on knotting, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

35. A sterile, surgical suture according to claim 1 having a needle attached to said core.

36. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is an aromatic polyamide.

37. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(p-Phenylene terephthalamide).

38. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(1,4-benzamide).

39. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

1/1

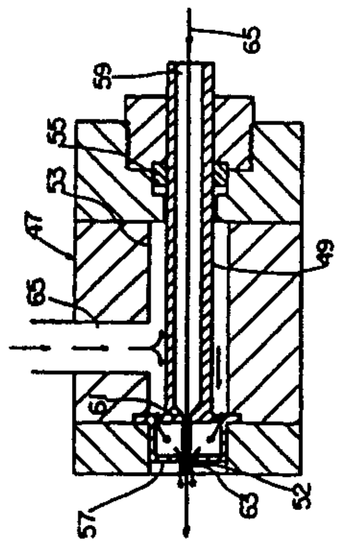

FIG. 3

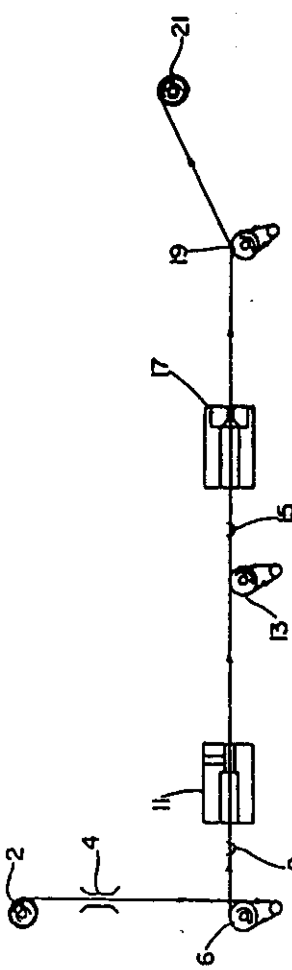

FIG. 1

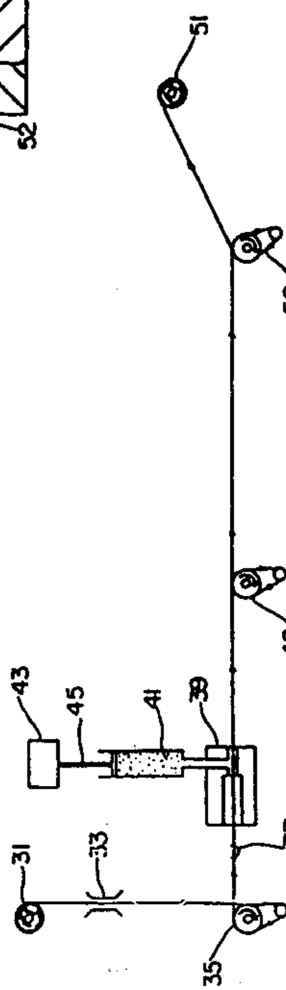

FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00918

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int Cl ^{3} A61L 17/00
US CL 128/335.5

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	128/329R, 334R-335.5, Dig. 8, Dig. 18 28/140, 165, 166, 169 66/169R-170, 202 8/Dig. 21 8/490, 529-533, 115.5-115.7, 130.1-132, Dig. 3,

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

cont'd Dig. 9

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
X, Y	US, A, 3,791,388	12 February 1974 HUNTER	1, 6-9, 11-17, 20, 23-35
Y	US, A, 4,014,973	29 March 1977 THOMPSON	23, 24, 31
Y	US, A, 3,359,983	26 December 1967 NORTHEY	5, 10, 23, 24, 39
Y	US, A, 3,630,205	28 December 1971 LISTNER	5, 10, 23, 24, 39
X, Y	US, A, 4,204,542	27 May 1980 BOKROS	23, 24, 35-38
X, Y	US, A, 4,336,357	22 June 1982 BARTOLI	23, 24, 35-38

* Special categories of cited documents: [15]
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
31 JULY 1984	17 AUG 1984
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	C. Fred Rosenbaum C. FRED ROSENBAUM

Form PCT/ISA/210 (second sheet) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000180

International Application No PCT/US84/00918

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V.☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.☐ Claim numbers , because they relate to subject matter [12] not required to be searched by this Authority, namely:

2.☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI.☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-24 and 35-39 are drawn to a surgical suture.

Claims 25-34 are drawn to a method of making a surgical suture.

1.☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2.☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3.☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4.☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (supplemental sheet (2)) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS

DMI000181

PTO-1683
(Rev. 7-96)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000183

HERMES DECLARATION
EXHIBIT 15 – PART 6 OF 8

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

February 04, 2005

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: *07/838,511*
FILING DATE: *February 19, 1992*
PATENT NUMBER: *5,314,446*
ISSUE DATE: *May 24, 1994*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

N. WOODSON
Certifying Officer

PART ~~1~~ 2 OF 2 PART(S)

Form PTO-1449	Docket No. ETH 782	Serial No. 07/838,391
List of Prior Art Cited by Applicant	Applicant Alastair Hunter et al.	
	2-19-92	Group 1504

U.S. PATENT DOCUMENTS

Exam'r Init.		Document No.	Date	Name	Class	Sub Class	File Date
CWR	AA	3,942,532	3/9/76	Hunter et al.	128	335.5	8/15/74
CWR	AB	4,624,256	11/25/86	Messier et al.	128	335.5	8/11/85
CWR	AC	3,527,650	9/8/70	Block, A.	117	7	12/21/67
CWR	AD	4,470,941	9/11/84	Kurtz, L.	264	136	6/2/82
CWR	AE	3,187,752	6/8/65	Glick, A.	128	335.5	4/27/62
CWR	AF	4,043,344	8/23/77	Landi et al.	128	335.5	9/20/76
CWR	AG	4,047,533	8/13/77	Perciaccante et al.	128	335.5	9/20/76
CWR	AH	4,946,467	8/7/90	Ohi et al.	606	228	3/8/89
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

Exam'r Init.		Document No.	Date	Country	Class	Sub Class	Translate Yes	No
CWR	AL	GB 2 218 312A	11/15/89	United Kingdom	A01K	91/00	✓	–
CWR	AM	DE 2949920	3/19/81	Germany	A61F	1/00	✓	–
CWR	AN	WO 86/00020	1/3/86	PCT	A61L	17/00	✓	–
	AO							
	AP							

OTHER REFERENCES (include author, title, date, pertinent pages, etc.)

	AR	
	AS	
	AT	

Examiner	Date Considered
CHRIS RAIMUND	JUNE 25, 1992

*Examiner: See note on original PTO form concerning initialing and MPEP 609 compliance. Include copy of this form with next communication to applicant.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000185

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER A	ETH-782

EXAMINER	
RAIMUND,C	
ART UNIT	PAPER NUMBER
1504	3

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

DATE MAILED: 07/08/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on ________ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ________

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.

   Of the above, claims 1 - 20 are withdrawn from consideration.

2. ☐ Claims ________ have been cancelled.
3. ☐ Claims ________ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims ________ are objected to.
6. ☑ Claims 1 - 24 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ________. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ________ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on ________, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ________; filed on ________.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000186

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, drawn to a heterogeneous braid, classified in Class 57, subclass 243.

II. Claims 21-24, drawn to a surgical suture, classified in Class 600, subclass 231.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew S. Goodwin on June 23, 1992 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-24. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A).

Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon. Such a braid is disclosed to have the low stretchability of polyethylene and the low coefficient of friction of polyester. (See page 1). It is therefore known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.

Braided sutures are well known in the art. Many of the requirements of sutures are comparable to those of fishing line-strength, low stretchability, flexibility, low coefficient of friction etc. Indeed, many of the same materials are used for both of these applications. It would therefore have been

obvious, in view of Burgess, to use a heterogeneous braid for a suture. Claims 21 and 23 are therefore unpatentable over Burgess.

Synthetic, fiber forming polymers are widely employed as filaments in braided sutures. In German Patent Application DE 2949920A1, for example, surgical sutures made from braided polytetrafluoroethylene (PTFE) fibers or polyester fibers are disclosed. As polyester fibers are noted for their strength and PTFE fibers for their low coefficient of friction, it would have been obvious to use a braid comprising both types of filaments as a suture.

It is also known in the art to a braid around longitudinally extending core filaments. Ohi et al, for example, disclosure a core comprising a plurality of synthetic fiber filaments (column 1, lines 57-60). Polyester filament are specifically disclosed (column 2, lines 4-9). It would therefore have been obvious to dispose a heterogeneous braid comprising polyester and polytetrafluoroethylene fibers around a core of polyester fibers to form a suture. Claims 22 and 24 are therefore unpatentable over Burgess.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.

Chris Raimund

Chris Raimund:jp
July 06, 1992

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

PTO FORM 948
(Rev 5-91)

GROUP 1504

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

ATTACHMENT TO PAPER NUMBER 3

APPLICATION NUMBER 838511

NOTICE OF DRAFTSMAN'S PATENT DRAWING REVIEW

The PTO Draftsmen review all originally filed drawings regardless of whether they were designated as informal or formal.

The drawings filed 2/19/92

A. ☒ are approved.

B. ☐ are objected to under 37 CFR 1.84 for reason(s) checked below. The examiner will require submission of new, corrected drawings at the appropriate time. Corrected drawings must be submitted according to the instructions listed on the back of this Notice.

1. Paper and ink. 37 CFR 1.84(a)
   ☐ Poor Quality Paper. Must Be White. Transparent Paper Not Allowed.
   Sheet(s) ____________

2. Size of Sheet and Margins. 37 CFR 1.84(b)
   Acceptable Paper Sizes and Margins

Paper Size

Margin	8 1/2 by 14 inches	8 1/2 by 13 inches	DIN size A4 21 by 29.7 cm.
Top	2 inches	1 inch	2.5 cm.
Left	1/4 inch	1/4 inch	2.5 cm.
Right	1/4 inch	1/4 inch	1.5 cm.
Bottom	1/4 inch	1/4 inch	1.0 cm.

☐ Proper Size Paper Required. All Sheets Must be Same Size.
Sheet(s) ____________

☐ Proper Margins Required.
Sheet(s) ____________
☐ Top ☐ Right
☐ Left ☐ Bottom

3. Character of Lines. 37 CFR 1.84(c)
   ☐ Lines Pale, Rough and Blurred, or Jagged. Fig(s) ____________

   ☐ Solid Black Shading Not Allowed.
   Fig(s) ____________

4. ☐ Photographs Not Approved.
   ____

5. Hatching and Shading. 37 CFR 1.84(d)
   ☐ Shade Lines are Required.
   Fig(s) ____________

   ☐ Criss-Cross Hatching Not Allowed.
   Fig(s) ____________

   ☐ Double Line Hatching Not Allowed.
   Fig(s) ____________

   ☐ Parts in Section Must be Hatched Properly. Fig(s) ____________

6. Reference Characters. 37 CFR 1.84(f)
   ☐ Reference Characters Poor or Rough and Blurred. Fig(s) ____________

   ☐ Minimum 1/8 inch (3.2 mm.) in height is required. Fig(s) ____________

   ☐ Figure Legends Poor or Placed Incorrectly. Fig(s) ____________

7. Views. 37 CFR 1.84(i) & (j)
   ☐ Figures Must be Numbered Separately.
   ____

   ☐ Figures Must Not be Connected
   Fig(s) ____________

8. Identification of Drawings. 37 CFR 1.84(l)
   ☐ Extraneous Matter or Copy Machine Marks Not Allowed. Fig(s) ____________

9. ☐ Changes Not Completed from Prior PTO-948 dated ____________

☐ Comments:

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000191

Telephone inquires concerning this review should be directed to the Chief Draftsman at telephone number (703) 557-6404.

JC
Reviewing Draftsman

3/6/92
Date

PTO Copy

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities—37 CFR 1.85**
   File new drawings with the changes incorporated therein. The art unit number, serial number and number of drawing sheets should be written on the drawings in accordance with 37 CFR 1.84(l). Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37). If delayed, the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for response in the "Notice of Allowability" (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.136. The drawing should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

   Timing of Corrections
   Applicant is required to submit **acceptable** corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTOL-37). Within that three month period, two weeks should be allowed for review by the Office of the correction. If a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon as possible.

   Failure to take corrective action within set (or extended) period will result in **ABANDONMENT** of the Application.

2. **Corrections other than Informalities Noted by the Draftsman on the PTO-948**
   All changes to the drawings, other than informalities noted by the Draftsman, **MUST** be made in the same manner as above except that, normally, a red ink sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

MAIL ROOM FEB 16 199_ 64 PAT. & TRADEMARK

ETH 782
Batch No. 567

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

February 14, 1994
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative
Hal Brent Woodrow
(Signature)
February 14, 1994
(Date of Signature)

9200 ordered 5/18/94

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT UNDER 37 CFR §312

Dear Sir:

This is responsive to the Examiner's Amendment attached to the Notice of Allowance dated November 15, 1993, at which time a shortened statutory period for response of three months was set.

In the Claims

Please amend the claims as follows:

In Claim 10 after "claim" and before "wherein" please delete "8" and insert therefor -- 21 -- .

OK to enter -

Hal Brent Woodrow
Hal Brent Woodrow
Reg. No. 32,501
Attorney for Applicant(s)

ETH-78

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

Matthew Goodwin
(Signature)

August 6, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the <u>most important requirement</u> for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have <u>poor</u> knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line <u>minimal</u> stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

low elongation and, in turn, poor knot strength properties. This is a good idea for a fishing line because high strength and low elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a

suture, then he would inevitably design an unacceptable suture. Accordingly, Applicants respectfully submit that the rejection is in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,

Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

Case Docket No.: ETH-782

Application of Alastair Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x $20	= $ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x $72	= $ XXX.XX
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ XXX.XX

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[ ] Charge $###.## to Deposit Account No. 10-750/DOCKET NO/ATTY. Three copies of this sheet are enclosed.

[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[ ] A check in the amount of $ ________ is attached.

Matthew S. Goodwin

Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

Case Docket No.: ETH-782

In re application of Alastair Hunter et al.

Serial No. 838,511

Filed February 19, 1992

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CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x $20	= $ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x $72	= $ XXX.XX
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ XXX.XX

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Matthew S. Goodwin

Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000199

MAIL ROOM AUG 76 1992 PAT. & TM. OFF.

Case Docket No.: ETH-782

154

Application of Alastair Hunter et al.

7-9-92
150

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

RECEIVED
AUG 17 1992
GROUP 150

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x $20	= $ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x $72	= $ XXX.XX
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ XXX.XX

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*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

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[ ] A check in the amount of $ ________ is attached.

Matthew S Goodwin

Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/...	02/13/92	HUNTER A	ETH-682

EXAMINER: RAIMUND, C

ART UNIT: 1... | PAPER NUMBER: 5

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

DATE MAILED: 11/02/92

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on August 6, 1992 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ______

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.

   Of the above, claims 1 - 20 are withdrawn from consideration.

2. ☐ Claims ______ have been cancelled.
3. ☐ Claims ______ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims ______ are objected to.
6. ☐ Claims ______ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ______. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ______, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed ______, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ______; filed on ______.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev.9-89)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000201

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 23 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Doddi et al.

Doddi et al disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56). The suture is specifically disclosed attached to a needle (column 11, lines 53-54). Claims 21 and 23 are therefore unpatentable over Doddi et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 22 and 24 are rejected under 35 U.S.C. § 103 as being unpatentable over Kaplan et al taken with Doddi et al.

Kaplan et al discloses a ligament prosthesis comprising a core component and a braided sheath component (see Figure 3). The core component is "made up of one or more biocompatible, essentially non-bioasborbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated "from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable" (column 9, lines 25-28).

Doddi et al disclose suitable biocompatible, non-absorbable fibers to include PET and PTFE (column 9, lines 51-53). It would have been obvious to form the device of Kaplan with a sheath component of PTFE and PET and a core component of PET. PTFE is known to impart improved knot run down properties to sutures (see Block U.S. Patent No. 3,527,650). PET is noted for its low cost

and high strength. Claims 22 and 24 are therefore unpatentable over Kaplan et al taken with Doddi et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.

Chris Raimund

Chris Raimund:jp
October 29, 1992

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

SEPARATE—HOLD TOP AND BOTTOM EDGES, SNAP-APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

SERIAL NO. 838,511

GROUP ART UNIT 1504

ATTACHMENT TO PAPER NUMBER

NOTICE OF REFERENCES CITED

APPLICANT(S) Hunter et al.

U.S. PATENT DOCUMENTS

*		DOCUMENT NO	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	4052988	10/1977	Doddi et al.	128	335.5	—
	B	5147400	09/1992	Kaplan et al.	623	13	09/1990
	C	5116360	05/1992	Pinchuk et al.	623	1	12/1990
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R	
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T	
U	

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000205

EXAMINER	DATE
CHRIS RAIMUND	OCT. 26, 1992

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

XR 4,052,988

United States Patent [19]

Doddi et al.

[11] 4,052,988

[45] Oct. 11, 1977

[54] SYNTHETIC ABSORBABLE SURGICAL DEVICES OF POLY-DIOXANONE

[75] Inventors: **Namassivaya Doddi; Charles C. Versfelt,** both of Somerville; **David Wasserman,** Springfield, all of N.J.

[73] Assignee: **Ethicon, Inc.,** Somerville, N.J.

[21] Appl. No.: **648,236**

[22] Filed: **Jan. 12, 1976**

[51] Int. Cl.^{2} A61L 17/00

[52] U.S. Cl. .... 128/335.5; 3/1; 128/92 B; 128/92 D; 260/78.3 R

[58] Field of Search 128/335.5, 92; 260/78.3; 3/1

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,063,967	11/1962	Schultz	260/78.3
3,063,968	11/1962	Schultz	260/78.3
3,190,858	6/1965	Cox et al.	260/78.3
3,297,033	1/1967	Schmitt et al.	128/335.5
3,636,956	1/1972	Schneider et al.	128/335.5
3,645,941	2/1972	Snapp et al.	260/78.3
3,867,190	2/1975	Schmitt et al.	128/335.5 X
3,960,152	6/1976	Augurt et al.	128/335.5

OTHER PUBLICATIONS

Palomaa et al.-Ber. Deut. Chem. Gesellsch., vol. 66B, pp. 1629-1632 (1933).

Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] **ABSTRACT**

Synthetic absorbable sutures and other surgical devices are prepared from polymers of p-dioxanone and 1,4-dioxepan-2-one, and alkyl substituted derivatives thereof. Monofilament sutures of oriented fibers are characterized by good tensile and knot strength and a high level of flexibility and softness. The sutures have good in vivo strength retention and are slowly absorbed without significant tissue reaction.

39 Claims, 5 Drawing Figures

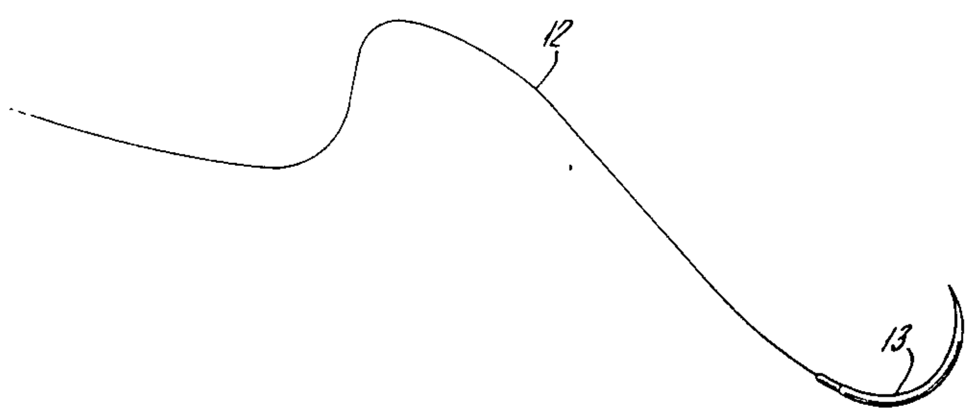


Fig. 1.

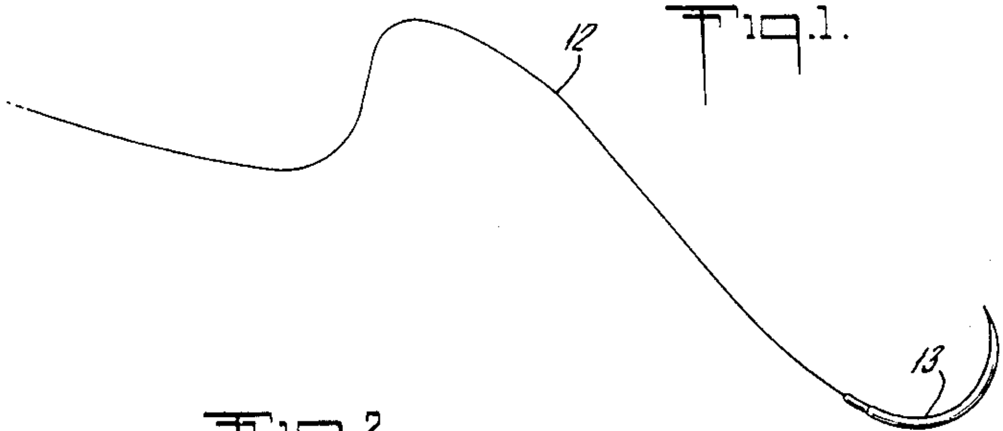


Fig. 2.

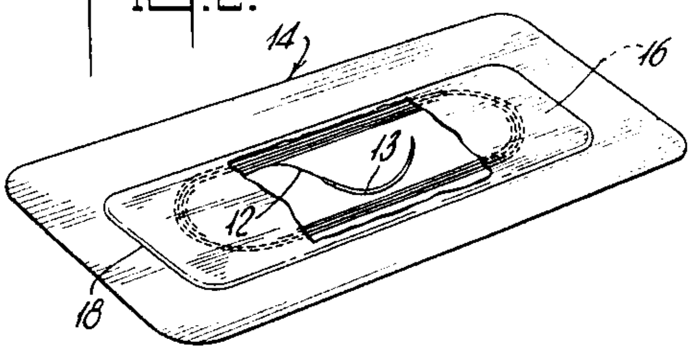


Fig. 3.

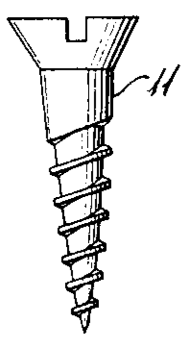


Fig. 4.

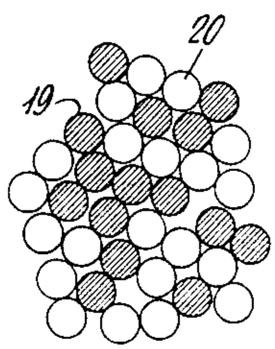
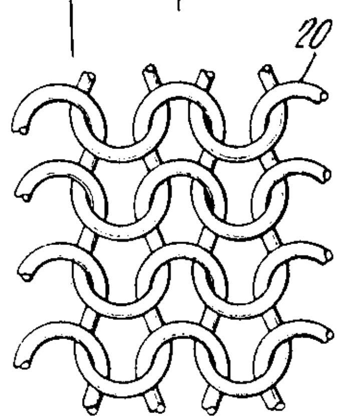


Fig. 5.



SYNTHETIC ABSORBABLE SURGICAL DEVICES OF POLY-DIOXANONE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to synthetic absorbable sutures, and more particularly, to synthetic absorbable sutures comprising extruded and oriented filaments of polymers of p-dioxanone or 1,4-dioxepan-2-one.

2. Description of Prior Art

Absorbable suture materials have traditionally been natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable sutures from polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable sutures are described in U.S. Pat. Nos. 3,636,956, 3,297,033 and elsewhere in the literature.

Among the requirements of an ideal absorbable suture are that it should have good handling properties, should approximate and hold tissue for proper healing with minimal tearing and tissue damage, should have adequate straight tensile and knot strength, should be controllably uniform in properties including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body or the condition of the patient, without causing such unfavorable tissue reactions as walling off, granuloma formation, excessive edema, etc., and finally should be capable of being properly and easily tied into surgical knots.

While multifilament sutures manufactured from polymers of lactide and glycolide fulfill the above requirements to a large degree, monofilament sutures of these materials are considerably less flexible than catgut and these synthetic sutures are accordingly generally limited to a multifilament, braided construction. Sutures of glycolide polymers are also not suitable for sterilization by radiation without suffering severe degradation of physical properties.

The present invention provides synthetic absorbable sutures having a high degree of softness and flexibility which allows the sutures to be used in monofilament form. The sutures can also be sterilized with cobalt 60 radiation without serious loss of suture strength. It is accordingly an object of the present invention to provide synthetic absorbable sutures having unique and desirable properties not available with the sutures of the prior art.

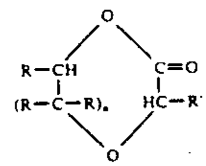
We have discovered that polymers of p-dioxanone and 1,4-dioxepan-2-one prepared from monomers of very high purity can be melt extruded into pliable, monofilament fibers which are slowly absorbed in animal tissue without significant adverse tissue reaction. The fibers have good tensile and knot strength and good in vivo strength retention, and can be sterilized with cobalt 60 without serious loss of these properties.

Polymers of p-dioxanone and fibers extruded therefrom have been known in the art. U.S. Pat. Nos. 3,063,967 and '968 for example, describe the polymerization of p-dioxanone and the preparation of films and fibers therefrom. The low tensile strength of fibers prepared in accordance with the teachings of these references, however, make these fibers generally unsuitable for use as surgical sutures. Moreover, there was no appreciation in these references of the absorbability of such fibers which were reported to be resistent to the effects of saline and distilled water.

Other references dealing with the polymerization of p-dioxanone include, but are not limited to, U.S. Pat. Nos. 3,190,858, 3,391,126 and 3,645,941 which disclose various catalysts for the polymerization of lactones such as p-dioxanone, and U.S. Pat. No. 3,020,289 which describes the polymerization of p-dioxanone in the presence of sulfuric acid. None of these references suggest polymers of p-dioxanone or 1,4-dioxepan-2-one for use in the preparation of synthetic absorbable sutures in accordance with the present invention.

SUMMARY

Synthetic absorbable sutures are prepared from polymers of monomers having the formula:



wherein R' and each R are hydrogen, methyl or ethyl and n is 1 or 2, provided that when n is 2, at least two R groups are hydrogen.

Polymers prepared by the polymerization of very pure monomers are melt extruded into filaments suitable for use as synthetic absorbable sutures. The filaments are characterized by high tensile and knot strength, good strength retention in vivo, and a Young's modulus of less than about 600,000 psi corresponding to a high degree of softness and flexibility.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a needle-suture combination;

FIG. 2 is a perspective view of a suture-needle combination within a hermetically sealed container;

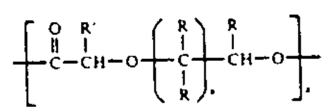
FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a surgical fabric knitted from fibers of the present invention.

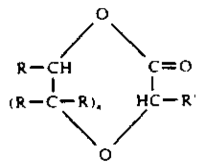
DESCRIPTION OF PREFERRED EMBODIMENTS

Polymers of the present invention are comprised of units having the general formula:



wherein R' and R are individually hydrogen, methyl, or ethyl, n is 1 or 2 provided that when n is 2 at least two R groups are hydrogen, and x is the degree of polymerization resulting in a fiber forming polymer.

The polymer is conveniently prepared from highly purified monomer, i.e., monomer of at least about 98 percent purity, having the formula:



wherein R, R' and n are as defined above. When n is 1, the monomer is preferably p-dioxanone, methyl-p-dioxanone, or dimethyl-p-dioxanone. When n is 2, the monomer is preferably 1,4-dioxepan-2-one.

A particularly preferred monomer is p-dioxanone, and the following description and examples which are presented by way of illustration are directed primarily to the preparation and polymerization of that monomer, it being understood that certain variations may apply to other monomers and polymers encompassed by the above formula as will be readily apparent to those skilled in the art. Para-dioxanone monomer is conveniently prepared by reacting ethylene glycol, metallic sodium, and chloroacetic acid as hereinafter described in detail. The resulting monomer is preferably purified to 99+% purity by multiple distillations and recrystallizations. We have discovered that high monomer purity is necessary to obtain a high molecular weight polymer and ultimately, a fiber of good tensile and dry knot strength.

The purified monomer is polymerized at a temperature of 20° to 130° C, most preferably above 75° C, in the presence of an organometallic catalyst as hereinafter described in detail to obtain a high molecular weight polymer of p-dioxanone characterized by an inherent viscosity of at least about 0.50 measured as a 0.1% solution in tetrachloroethane at 25° C, and a crystallinity of at least about 20% as determined by X-ray diffraction.

The polymer is melt extruded through a spinneret in a conventional manner to form one or more filaments which are subsequently drawn about 4x to 6x in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments have good tensile and dry knot strength and good in vivo strength retention.

To further improve dimensional stability and tensile strength retention, the oriented filaments may be subjected to an annealing treatment. This optional annealing treatment consists of heating the filaments to a temperature of from about 50° to 105° C, most preferably from about 50° to 80° C while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 50° to 80° C for up to about 24 hours is satisfactory for p-dioxanone. Optimum annealing time and temperature for maximum improvement in fiber in vivo strength retention and dimensional stability is readily determined for each fiber composition.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent separation as a result of movement or exercise, a suture must meet certain minimum standards of strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Oriented filaments of the present invention are characterized by a straight tensile strength of at least about 40,000 psi and a knot strength of at least about 30,000 psi, although significantly higher strengths are possible as will be apparent from the following examples.

The preparation of high molecular weight oriented filaments of poly-p-dioxanone and other polymers of the present invention is further illustrated by the following examples where all percentages are by weight unless otherwise noted.

EXAMPLE I

A. Preparation of p-dioxanone

Metallic sodium is dissolved in a large excess of ethylene glycol to obtain a glycolate which is further reacted with about 0.5 mols of chloroacetic acid per mole of sodium to yield the sodium salt of the hydroxy acid. Excess ethylene glycol and by-products of the reaction are removed by distillation and by washing with acetone. The sodium salt is converted to the free hydroxy acid by the addition of hydrochloric acid, and the resulting sodium chloride is removed by precipitation with ethanol followed by filtration.

The hydroxy acid filtrate is slowly heated up to about 200° C, preferably in the presence of $MgCO_3$, to remove alcohol and water by distillation. Upon further heating at atmospheric pressure the p-dioxanone is formed and distills over at a head temperature of between about 200°-220° C. The purity of the crude dioxanone product is generally about 60-70 percent as determined by gas chromatography and yields are in the order of 50 to 70 percent.

The crude p-dioxanone is further purified to about 98 percent by redistillation, and finally purified to 99+% by multiple crystallizations and/or distillation.

B. Polymerization of p-dioxanone

Highly purified p-dioxanone is polymerized in the presence of an organometallic catalyst such as diethyl zinc or zirconium acetylacetonate to obtain high molecular weight, fiber forming polymers according to the following typical procedure.

0.1 M (10.2 g) of dry, 99+% pure p-dioxanone monomer is weighed into a dry flask under an inert atmosphere of dry nitrogen and 0.36 ml of 0.138M diethyl zinc in heptane are added. The monomer to catalyst ratio is calculated as 2000 : 1. After completely mixing the catalyst and monomer, the flask is swirled at intervals over a period of about one hour or less at room temperature until initiation and polymerization is evident by the occurrence of gelation. The flask is then connected to a vacuum of about 14 inches of Hg. The sealed flask is maintained at 80° C in a constant temperature bath for about 72 hours to complete the polymerization. The resulting polymer is characterized by an inherent viscosity I.V. of 0.70 measured on a 0.1% solution of polymer in tetrachloroethane at 25° C, a glass transition temperature T_g of −16° C, a melting temperature T_m of 110° C, and a crystallinity of 37 percent.

In the polymerization procedure, the initial one hour hold time for polymerization initiation is required only when using volatile catalysts which would be lost if the polymerization mixture was immediately placed under vacuum. When nonvolatile catalysts such as zirconium acetyl acetonate are used, this hold time may be omitted and the polymerization reaction mixture placed under vacuum immediately following addition and mixing of catalyst. As a further alternative, the entire polymeriza-

tion reaction may be conducted under an inert atmosphere at atmospheric pressure.

C. Polymer Extrusion

The polymer obtained in the preceding step is thoroughly dried and melt extruded through a spinnerette using conventional textile fiber spinning procedures to obtain one or more continuous monofilament fibers suitable for use as synthetic absorbable sutures. The spun filaments are drawn about 5x at a temperature of about 43° C to increase molecular orientation and enhance physical properties, particularly tensile strength. The drawn monofilaments having a diameter of about 11 mils corresponding to a size 2-0 suture are characterized by an inherent viscosity of 0.64, a crystallinity of 30 percent, a straight tensile strength of 36,600 psi, an elongation of 99.4 percent, and a knot strength of 31,900 psi.

EXAMPLE II

The method of Example I was repeated using 0.13 ml of zirconium acetyl acetonate catalyst (7500 : 1 monomer to catalyst ratio) in the polymerization reaction. Properties of polymer and fiber were as follows:

Polymer

I.V.: 0.71
Tg: −16° C
Tm: 111° C
Crystallinity: 49%

Fiber

I.V.: 0.57
Tensile Strength: 38,600 psi
Elongation: 88.5 percent
Knot Strength: 32,300 psi

EXAMPLE III

Polydioxanone polymers were prepared in accordance with the polymerization method of Example I using 0.20 ml of zirconium acetyl acetonate catalyst (5000 : 1 monomer to catalyst ratio) and a polymerization temperature of 90° C. Polymer properties were as follows:

I.V.: 0.65
Tg: −19° C
Tm: 109° C
Crystallinity: 35%

EXAMPLE IV

The method of Example III was repeated using 0.50 ml of zirconium acetylacetonate catalyst. (2000 : 1 monomer to catalyst ratio). Polymer properties were as follows:

I.V.: 0.59
Tg: −17° C
Tm: 111° C
Crystallinity: 44%

EXAMPLE V

The method of Example I was repeated at a monomer to catalyst ratio of 4000 : 1 and with a polymerization reaction of three days at 80° C. The resulting polymer had an inherent viscosity of 0.86 and crystallinity of 30 percent. Fibers extruded from the polymer and drawn 6x at 87° C had a diameter of 9 mils, a straight tensile strength of 65,100 psi, elongation of 47.6%, and knot strength of 46,400 psi.

EXAMPLE VI

The method of Example I was repeated using tetraoctylene glycol titanate as the polymerization catalyst. The monomer to catalyst ratio was 12,300 : 1 based on titanium content, and the polymerization reaction was maintained at 80° C for six days. The resulting polymer had an inherent viscosity of 0.86 and a crystallinity of 33 percent. Extruded filaments drawn 6x at 83° C had a diameter of 11 mils, a tensile strength of 55,600 psi, a dry knot strength of 48,800 psi, and a Young's modulus of 167,000 psi.

EXAMPLE VII

Two lots of polydioxanone were prepared according to the method of Example VI using a monomer to catalyst ratio of 26,700 : 1 and with a polymerization reaction of six days and 12 days. The resulting polymers had inherent viscosities of 0.81 and 0.84 respectively. The polymers were combined and extruded into fiber which, after drawing 6x, had the following physical properties.

Fiber Diameter: 9 mils
Tensile Strength: 70,600 psi
Elongation: 46.3
Dry Knot Strength: 50,300 psi

The monofilament fibers had a high degree of softness and pliability.

EXAMPLE VIII

In Vivo Absorption

Two 2 cm segments of monofilament fiber from Example I having a diameter corresponding to size 2-0 suture were implanted aseptically into the left gluteal muscles of 24 female Long Evans rats. The implant sites were recovered after periods of 60, 90, 120 and 180 days and examined microscopically to determine the extent of absorption.

After 60 days the suture cross sections were still transparent and intact. The tissue reactions were slight and most sutures were encapsulated with fibrous tissue. The sutures at this period remained birefringent under polarized light.

At 90 days the sutures were becoming translucent and had lost some of their birefringent properties. A few of the suture cross sections stained pink (eosinophilic) around the periphery and the edges were indistinct, indicating the onset of absorption. The tissue reactions generally consisted of a fibrous capsule and a layer of macrophages interposed between it and the suture surface.

At 120 days the sutures were translucent, most cross sections had taken on an eosinophilic stain, and the sutures appeared to be in the process of active absorption. The tissue reactions consisted of an outer layer of fibroblasts with an interface of macrophages several cell layers thick. Absorption at 120 days was estimated to be approximately 70 percent complete.

At 180 days, absorption of the suture was substantially complete. The incision healed with minimal adverse tissue reaction.

EXAMPLE IX

In Vivo Strength Retention

Segments of the sutures of several Examples were implanted in the posterior dorsal subcutis of female Long Evans rats for periods of 14, 21 and 28 days. The

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
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sutures were recovered at the designated periods and tested for straight tensile strength with the following results.

Test	Fiber	Implantation Time Days	Tensile Strength Pounds	Strength Retention %
a)	EX. I -	0	3.37	
		14	1.46	43.4
		21	1.14	33.8
		28	—	—
b)	EX. I - (Sterilized)[1]	0	3.08	
		14	1.16	37.6
		21	0.97	31.4
		28	0.70	22.9
c)	EX. VI - (Unannealed)	0	3.47	
		14	2.27	65.3
		21	1.62	46.7
		28	1.53	44.1
d)	EX. VI - (Annealed)[2]	0	6.47	
		14	5.39	83.3
		21	4.87	75.3
		28	4.30	66.5
e)	EX. VI - (Annealed)[2,3]	0	3.82	
		14	2.07	54.0
		21	1.36	35.5
		28	0.68	17.8
f)	EX. V - (Sterilized)[1]	0	4.05	
		14	2.77	68.4
		21	2.40	59.3
		28	2.15	53.2
g)	EX. V - (Sterilized)[3]	0	3.45	
		14	2.11	61.3
		21	1.36	39.3
		28	0.92	26.6

[1]Sterilized with ethylene oxide at 30° C.
[2]Annealed under nitrogen 24 hours at 65° C.
[3]Sterilized with cobalt 60.

EXAMPLE X

Small quantities of polydioxanone polymer were prepared in accordance with the general method of Example I using chromatographically pure p-dioxanone monomer and diethyl zinc and tetraoctylene glycol titanate as catalysts. Polymer prepared with diethyl zinc catalyst at a monomer to catalyst ratio of 4,000 and with a polymerization reaction of three days at 80° C had an inherent viscosity of 1.18. Polymer prepared with tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 12,250 and with a polymerization reaction of 6 days at 80° C had an inherent viscosity of 1.15. A second batch of high purity p-dioxanone monomer twice distilled in an annular still under a vacuum of 0.10–0.15 mm Hg was polymerized in the presence of tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 13,300 and at 80° C for 6 days. The resulting polymer had an inherent viscosity of 2.26.

EXAMPLE XI

Preparation of Methyl-p-Dioxanone

Following the general procedure of Example I,, metallic sodium was dissolved in a large excess of 1,2-propane diol and chloroacetic acid was added at 110°–115° C. Excess diol was removed by distillation and the sodium salt of the hydroxy acid converted to free acid by the addition of water and hydrochloric acid. Sodium chloride was precipitated by the addition of ethanol and removed by filtration. The resulting product was distilled in the presence of M_2CO_3 to remove excess alcohol and water and to recover crude methyl dioxanone monomer as a distillate at 196° to 202° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

EXAMPLE XII

Preparation of Dimethyl-p-Dioxanone

The procedure of Example XI was repeated reacting metallic sodium with 2,3-butanediol and choroacetic acid at about 130° C. Crude dimethyl dioxanone monomer was recovered from the distillation at 190° to 213° C. After purification the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

EXAMPLE XIII

Preparation of 1,4-dioxepan-2-one

The procedure of Example VI was repeated reacting metallic sodium with 1,3-propane diol and chloroacetic acid. Crude 1,4-dioxepan-2-one monomer was recovered from the distillation at 300° to 310° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

We have discovered that exceptionally high purity of p-dioxanone monomer is required to obtain polymers having a sufficiently high inherent viscosity to yield strong fibers upon extrusion. In general, the monomers are purified to 99+% by distillation and recrystallization prior to polymerization, and the resulting polymers have an inherent viscosity of at least about 0.50, and preferably 0.80 or higher measured as above described. As illustrated in Example X, polymers prepared from highly purified dioxanone have inherent viscosities well in excess of 1.10.

Drawn fibers of polydioxanone possess an unique combination of desirable properties. In particular, the monofilament fibers combine high tensile strength and knot strength with a pliability not to be found in any previous absorbable suture material, natural or synthetic. For example, the Young's modulus of the polydioxanone fiber of Example VI was 167,200 psi. In comparison, the Young's modulus for monofilament polyglycolide fibers and for 90/10 glycolide/lactide copolymer fibers is about 1 - 2 million psi, while that for moist catgut is about 350,000 psi. The low Young's modulus of polydioxanone makes this fiber particularly well suited for use as an absorbable monfilament suture, whereas prior synthetic absorbable sutures have largely been limited to braided, multifilament constructions which tend to be softer and more flexible than corresponding sizes of monofilament material. Monofilamented sutures are, of course, preferred for use in many surgical applications such as in ophthalmic procedures where smoothness of the suture surface is of particular importance.

The polymers of p-dioxanone of the present invention are also unique as compared with prior synthetic absorbable materials in that the sutures of these polymers can be sterilized by cobalt 60 radiation as well as by ethylene oxide. As illustrated in Example IX, while cobalt 60 sterilization results in some reduction in fiber strength and some increase in the in vivo rato of strength loss, the sterilized fiber nevertheless retains sufficient strength initially and for 28 days in vivo to make the fiber suitable for use in surgical procedures.

While the preceding examples have been directed to the preparation of homopolymers of p-dioxanone, methyl dioxanone, dimethyl dioxanone, and 1,4-dioxepan-2-one, these examples are for purposes of illustration only and are not limiting of the invention. Mixtures

of these polymers, copolymers of two or more of the above enumerated monomers, and copolymers of these monomers with up to about 50% by weight of other copolymerizable monomers which produce non-toxic and absorbable polymers are likewise included within the present invention. For example, such copolymers of dioxanone with lactide and/or glycolide are useful in the preparation of absorbable sutures, and the physical and chemical properties of such sutures such as strength, stiffness, and rate of absorption can be controlled by varying the relative proportions of the monomer constituents. In addition, the copolymers may be prepared by random, block or graft polymerization techniques in order to obtain particular combinations of compositions and physical and chemical properties. In certain applications where the rate of absorption of polydioxanone is less than desired, copolymers of dioxanone with from about 5 to 25 percent or more glycolide having a faster rate of absorption may be preferred.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the sutures. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis 2-methoxyethyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments even more pliable, but it also helps in spinning. As used herein, the term "inert" means materials that are chemically inert to the polymer, and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed.

Filaments of the present invention are adversely affected by moisture and are accordingly preferably packaged in a substantially moisture free environment and in hermetically sealed packages, a preferred form of which is shown in FIG. 2. In FIG. 2, there is shown a suture package 14 having disposed therein a coil of suture 12, one end of which is attached to needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or filled with a dry atmosphere such as air or nitrogen. The package is fabricated of two sheets of aluminum foil or an aluminum foil-plastic laminate and heat sealed or bonded with adhesive at the skirt 16 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

Filaments of the present invention may be used as monofilament or multifilament sutures, or may be woven, braided, or knitted either alone or in combination with absorbable fibers such as polyglycolide or poly (lactide-co-glycolide), or with non-absorbable fibers such as nylon, polypropylene, polyethyleneterephthalate, or polytetrafluoroethylene to form multifilament sutures and tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like.

Multifilament yarns that contain polymer filaments of the present invention together with nonabsorbable filaments are illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross section 19. In FIG. 4, the fibers 20 are extruded from homopolymer or copolymer compositions of the present invention as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants. Methods of weaving and crimping vascular prostheses are described in U.S. Pat. 3,096,560.

Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting, and fabricating by the nonwoven felting of fibers are described in U.S. Pat. No. 3,108,357 and U.S. Pat. No. 3,463,158. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of the polymers of this invention. The surgical utility of "bicomponent filaments" containing absorbable and nonabsorbable compenents is described in U.S. Pat. No. 3,463,158, the teaching of which is incorporated herein by reference. Monofilaments of the polymers of the present invention may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney, and other internal organs.

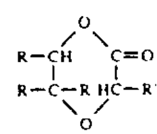
The products of the invention are useful in surgical applications where an absorbable aid or support is required, as for example, in the formation of surgical mesh, absorbable staples, artifical tendons, or cartilage material, and in other uses where a temporary aid during healing is needed. They may also be used to advantage in repairing hernias and in anchoring organs which have become loose.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such a scleral buckling prostheses. Thus, cylindrical pins, screws as illustrated in FIG. 3, reinforcing plates, etc., may be machined from the cast polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

Many different embodiments of this invention will be apparent to those skilled in the art and may be made without departing from the spirit and scope thereof. It is accordingly understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

We claim:

1. A sterile, synthetic absorbable suture comprising oriented fiber of a polymer of a monomer having the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

2. A suture of claim 1 wherein R and R' are hydrogen and the monomer is p-dioxanone.

3. A suture of claim 2 wherein said polymer is characterized by an inherent viscosity greater than about 0.50 measured as 0.1% solution of polymer in tetrachloroethane at 25° C.

4. A suture of claim 3 comprising a homopolymer of p-dioxanone.

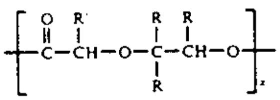
5. A suture of claim 1 comprising a polymer of methyl-p-dioxanone.

6. A suture of claim 1 comprising a polymer of dimethyl-p-dioxanone.

7. A suture of claim 1 comprising a copolymer of more than 50% by weight p-dioxanone and less than 50% by weight of at least one other monomer copolymerizable with p-dioxanone to an absorbable polymer.

8. A suture of claim 7 wherein said copolymer is of p-dioxanone and glycolide or lactide.

9. A sterile synthetic absorbable suture comprising oriented fiber of a polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strenght of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

10. A suture of claim 9 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

11. A suture of claim 10 wherein the inherent viscosity of said polymer is at least 0.80.

12. A suture of claim 9 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

13. A suture of claim 12 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

14. A suture of claim 9 wherein said polymer is a homopolymer of methyl-p-dioxanone or copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

15. A suture of claim 9 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

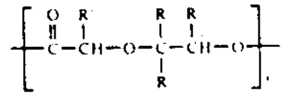
16. A suture of claim 1 having a surgical needle attached to at least one end thereof.

17. A needle and suture combination of claim 16 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

18. A suture of claim 9 having a surgical needle attached to at least one end thereof.

19. A needle and suture combination of claim 18 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

20. A surgical prosthesis comprising a fabric manufactured at least in part from synthetic absorbable fibers of a polymer having units of the formula:



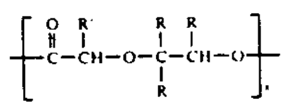
wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said fibers being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

21. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of p-dioxanone or a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

22. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

23. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

24. A surgical prosthesis comprising a solid surgical aid formed from an absorbable polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said prosthesis being dry to the extent of being substantially free of moisture.

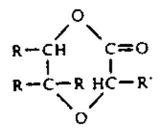
25. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

26. A surgical prosthesis of claim 24 wherein said polymer is a copolymer of at least 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

27. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of methyl-p-dioxanone or acopolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

28. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

29. A method of closing a wound in living tissue which comprises approximating the edges of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer of a monomer having the formula:



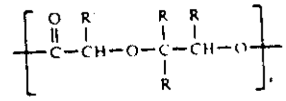
wherein R' and R are individually hydrogen, methyl or ethyl, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

30. A method of claim 29 wherein R and R' are hydrogen and the monomer is p-dioxanone.

31. A method of claim 29 wherein the monomer is methyl-p-dioxanone.

32. A method of claim 29 wherein the monomer is dimethyl-p-dioxanone.

33. A method of closing a wound in living tissue which comprises approximating the edge of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, and x is the degree of polymerization resulting in a fiber forming polymer, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

34. A method of claim 33 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1 percent solution of tetrachloroethane at 25° C.

35. A method of claim 34 wherein the inherent viscosity of said polymer is at least 0.80.

36. A method of claim 33 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

37. A method of claim 36 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

38. A method of claim 33 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

39. A method of claim 33 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

* * * * *

US005147400A

United States Patent [19]

Kaplan et al.

[11] Patent Number: 5,147,400

[45] Date of Patent: Sep. 15, 1992

[54] CONNECTIVE TISSUE PROSTHESIS

[75] Inventors: Donald S. Kaplan, Weston; John Kennedy, Stratford; Ross R. Muth, Brookfield, all of Conn.

[73] Assignee: United States Surgical Corporation, Norwalk, Conn.

[21] Appl. No.: 581,462

[22] Filed: Sep. 12, 1990

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 349,648, May 10, 1989, Pat. No. 4,990,158.

[51] Int. Cl.[5] A61F 2/08

[52] U.S. Cl. 623/13; 623/1; 623/11; 623/66

[58] Field of Search 623/1, 13, 11

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Primary Examiner—David Isabella
Assistant Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Thomas R. Bremer; Peter G. Dilworth; Rocco S. Barrese

[57] ABSTRACT

A semi-bioabsorbable connective tissue prosthesis, e.g., a replacement for the human anterior cruciate ligament, is provided whose stress-strain characteristics closely match those of the natural tissue.

58 Claims, 5 Drawing Sheets

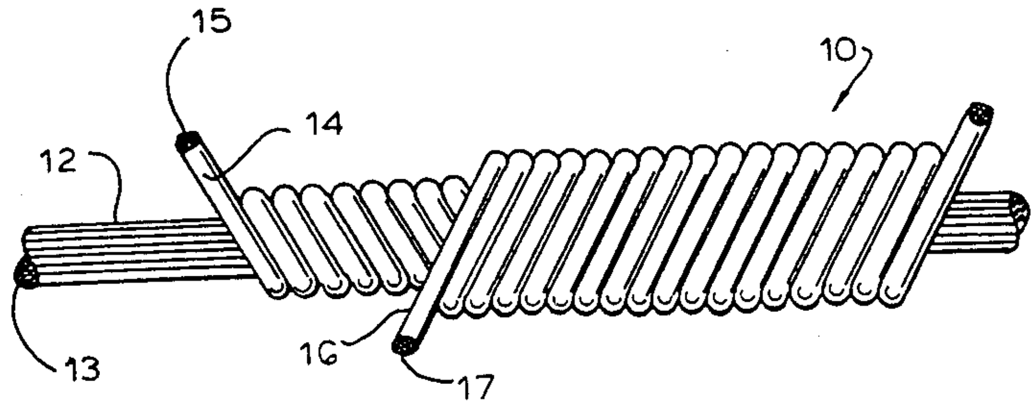
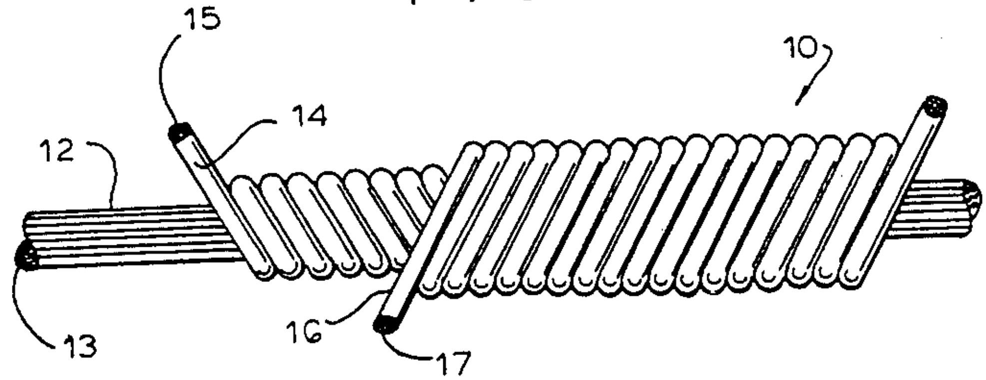


FIG. 1



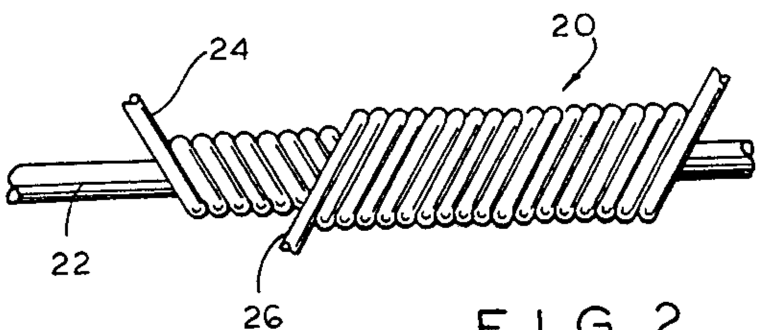


FIG. 2

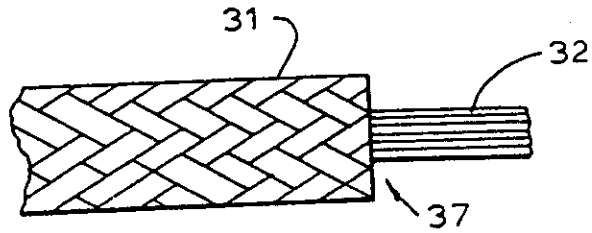
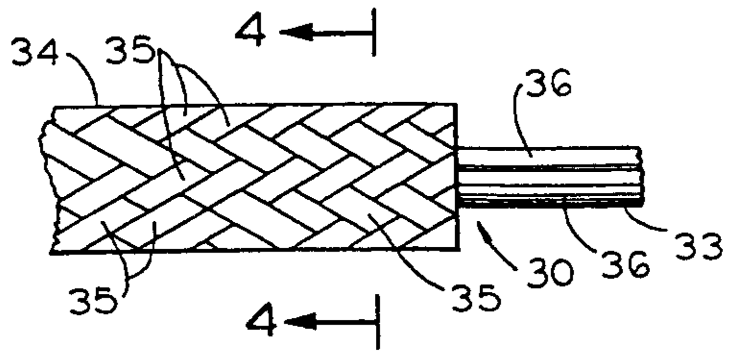


FIG. 5

FIG. 3



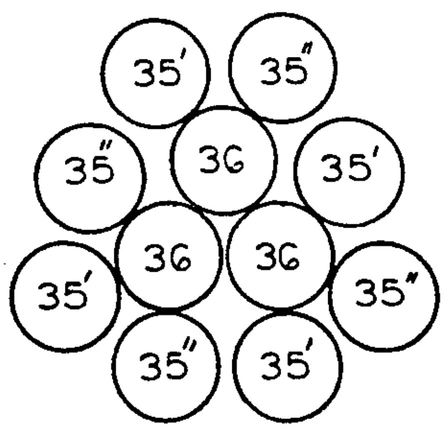
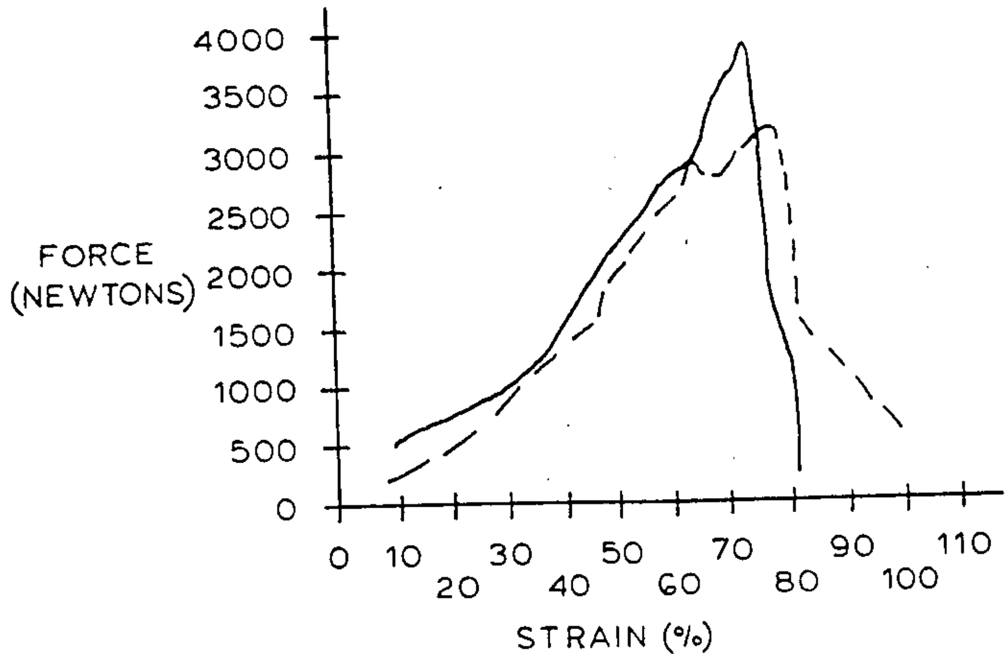


FIG. 4

FIG. 6



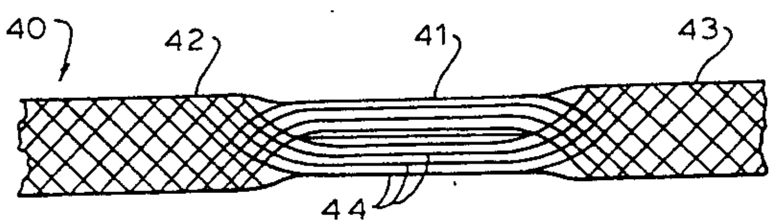


FIG. 7

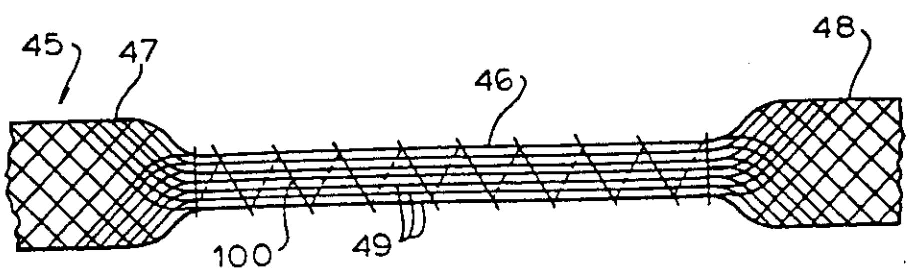


FIG. 8

FIG. 9

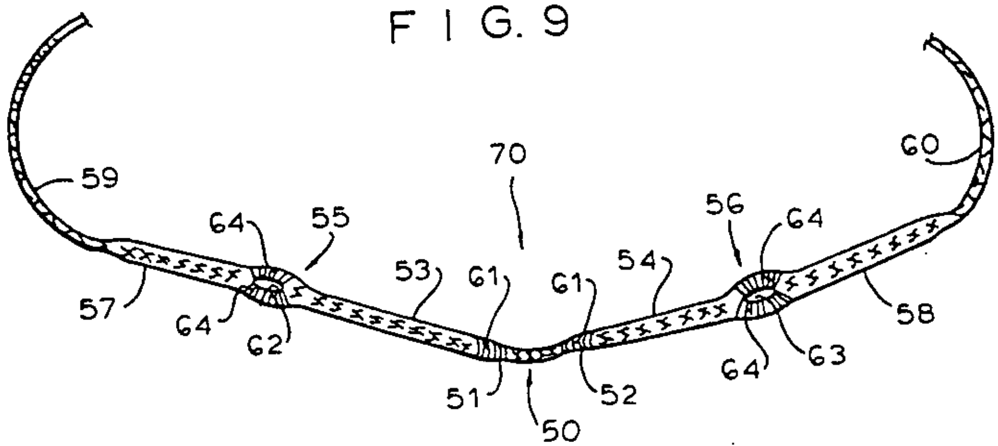


FIG. 10

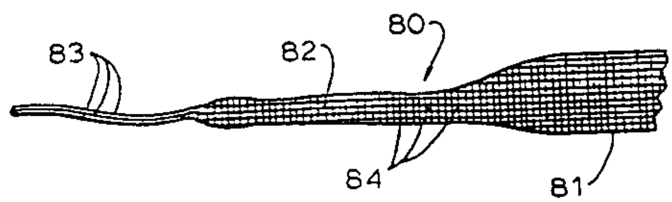


FIG. 11

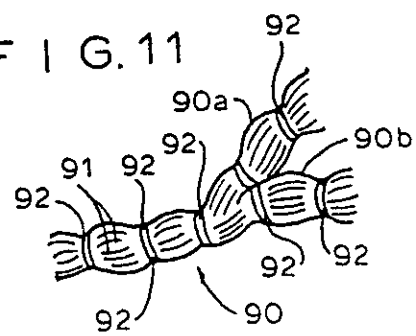
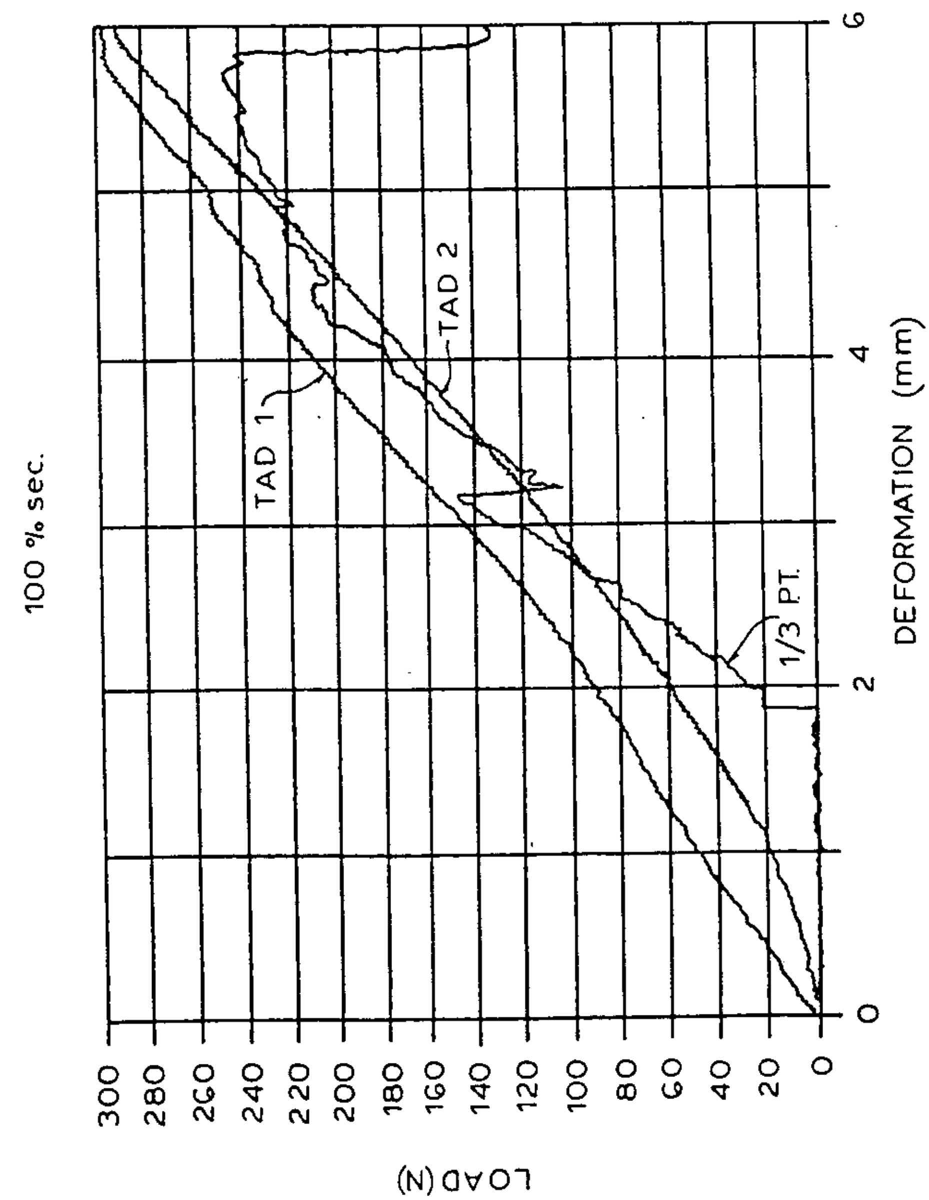


FIG. 12

TENSILE TESTS



CONNECTIVE TISSUE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

The application is a continuation-in-part of commonly assigned, co-pending U.S. patent application Ser. No. 349,648, filed May 10, 1989, now U.S. Pat. No. 4,990,158.

BACKGROUND OF THE INVENTION

This invention relates to a connective tissue prosthesis and, in particular, to a biocompatible ligament or tendon prosthesis which closely approximates the biomechanical characteristics of the natural tissue to be replaced or augmented.

Numerous connective tissue materials and constructions have been proposed for use as temporary or permanent grafts in ligament and tendon repair. Feagin, Jr., Ed., *The Crucial Ligaments/Diagnosis and Treatment of Ligamentous Injuries About the Knee* (Churchhill Livingstone, N.Y., 1988) describes a number of partially bioabsorbable materials which have been investigated for use as ligament grafts. In Chapter 33 of this publication (Rodkey, "Laboratory Studies of Biodegradable materials for Cruciate Ligament Reconstruction"), it is reported that while a 100 percent biodegradable ligament fabricated from polyglycolic acid (PGA) was found to be safe, strong, well-tolerated and provided stability for the repaired anterior cruciate ligament in dogs, its complete resorption within five weeks makes it unsuitable for use in prostheses intended for humans since a human ligament prosthesis must provide support over a much longer period of time. It is further reported that a study in dogs of the intraarticular use of a partially biodegradable ligament prosthesis possessing a Dacron (i.e., DuPont's polyethylene terephthalate (PET)) and PGA core and a separate outer sleeve woven from PGA and Dacron of a different percentage of composition gave disappointing results.

U.S. Pat. Nos. 4,792,336 and 4,942,875 describe a surgical device for repairing or augmenting connective tissue and comprising a plurality of fibers, in which the majority of the fibers are in a direction essentially parallel to the length of the device and can be either 100 percent bioabsorbable or can contain a nonabsorbable component. Additionally, sleeve yarns consisting completely of absorbable material wrap around these axial or warp yarns.

Biomedical Business International Report No. 7041 (Second Revision, May 1986), "Orthopaedic and Diagnostic Devices", pages 5—5 to 5-12, identifies a variety of materials which have been used in the fabrication of prosthetic ligaments including carbon fiber, expanded Teflon (i.e., DuPont's polytetrafluoroethylene), a combination of silicone and PET, polypropylene, polyethylene, nickel-chromium alloy fibers individually enclosed in synthetic textile or natural silk, carbon material coated with gelatin, polyester combined with PET fibers, bovine tissues, and others.

Other disclosures of ligament and tendon repair devices are provided, inter alia, in U.S. Pat. Nos. 3,805,300; 4,187,558; 4,301,551; 4,483,023; 4,584,722; 4,610,688; 4,668,233; 4,775,380; 4,788,979; and PCT Patent Publication No. WO 89/01320.

Chapter 33 (page 540) of the Feagin, Jr. publication referred to above identifies the characteristics of an ideal ligament prosthesis as follows:

(1) it must be durable with adequate strength to withstand the extreme forces placed upon it, yet compliant enough to allow for repetitive motion without failure or excessive creep elongation;

(2) it must be tolerated by the host with no antigenic or carcinogenic reaction;

(3) if partially or completely biodegradable, the size of the individual fibers and the construction pattern must be appropriate to support and allow eventual reconstitution of the repaired structure with ingrowth of fibrous tissue that matures to normal or near normal collagen;

(4) it must tolerate sterilization and storage; and

(5) it should be easily implanted using surgical and potentially arthroscopic techniques.

The existence of so many different types of materials and devices for use in connective tissue repair, some of which have been identified above, bears testimony to the difficulty of meeting some, much less all, of the foregoing characteristics in a single prosthetic device.

SUMMARY OF THE INVENTION

It is a principal object of the invention to provide a semi-bioabsorbable or fully bioabsorbable connective tissue prosthesis, e.g., a ligament or tendon repair device, which exhibits the stress-strain properties of the natural tissue to be replaced or augmented.

It is a specific object of the invention to provide the foregoing connective tissue prosthesis as a structure formed from a composite yarn comprising a non-bioabsorbable core yarn surrounded by a bioabsorbable or semi-bioabsorbable cover or sheath yarn.

It is a further specific object of the invention to provide a connective tissue prosthesis formed from a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-bioabsorbable sheath yarn, so as to exhibit the stress-strain properties of natural tissue.

It is another specific object of the invention to provide a prosthetic replacement for a human anterior cruciate ligament which is based on the aforesaid structure, in particular, one fabricated from a yarn whose sheath yarn component is derived from a glycolide-lactide copolymer.

In keeping with these and other objects of the invention, there is provided a connective tissue prosthesis comprising:

(a) a core made up of a first biocompatible composite yarn extending in the lengthwise direction; and

(b) a sheath surrounding the core and fabricated from a second biocompatible yarn,

wherein the first composite yarn in the core (a) comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The second biocompatible yarn forming the sheath (b) may be the same as, or different from, the first composite yarn which forms the core (a). More specifically, the second biocompatible yarn may also comprise a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semibioabsorbable sheath yarn component.

Also in keeping with the above and other objects of the invention, a connective tissue prosthesis is provided which comprises a tubular component fabricated from

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000221

composite yarn, the yarn comprising a biocompatible, nonbioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The foregoing connective tissue prostheses meet the Feagin, Jr. criteria, identified sucra, to a surprising degree. Due to elasticity of the composite yarn core component and relative inelasticity of the composite yarn sheath component, the stress-strain characteristics of the connective tissue prostheses closely match those of the natural tissue which they replace and their resorption properties can be calibrated to maintain the functionality of the prostheses throughout the entire period of the tissue regeneration process. The prostheses of this invention are readily sterilizable, possess good storage stability when suitably protected from hydrolytic forces, and can be installed at a ligament, tendon, vascular, or tracheal repair site employing known surgical reconstruction techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are enlarged isometric views of composite yarns which are utilized in the construction of the connective tissue prosthesis herein;

FIG. 3 is an enlarged isometric view of an alternative composite yarn utilized in the construction of the connective tissue prosthesis herein;

FIG. 4 is a schematic, cross-sectional view along line 4—4 of FIG. 3;

FIG. 5 represents a section of a ligament prosthesis manufactured from the composite yarn of FIG. 1 and suitable for use in the surgical reconstruction of the human anterior cruciate ligament;

FIG. 6 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 5 compared with the stress-strain characteristics of a natural ligament as reported in the literature;

FIG. 7 represents a section of a tubular ligament prosthesis manufactured from the composite yarn of the present invention and having an unbraided center section;

FIG. 8 represents a section of a tubular ligament prosthesis similar to FIG. 7 and additionally having the unbraided center section helically wrapped with a yarn;

FIG. 9 represents a section of a braided prosthesis manufactured from composite yarn of the present invention and modified in various fashion over the length thereof;

FIG. 10 represents a section of a tubular braided prosthesis manufactured from composite yarn of the present invention and provided with threading means;

FIG. 11 represents a section of a prosthesis manufactured from composite yarn of the present invention in which the prosthesis is branched; and

FIG. 12 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 7 compared with a canine patellar tendon.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, composite yarn 10 comprises a core yarn component 12 made up of a multiplicity of individual biocompatible, essentially non-bioabsorbable and preferably elastic filaments 13, advantageously provided with a slight to moderate twist, and a sheath yarn component 14 made up of a multiplicity of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 15 wound in a first direction around the core and an external multifilamentous sheath yarn component 16, also made up of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 17, wound in a second and opposite direction around sheath yarn component 14. For example, multifilamentous sheath yarn component 16 may comprise both absorbable and non-absorbable filaments 17. Generally, the filaments 13 of core yarn component 12 are substantially parallel.

Non-bioabsorbable core yarn component 12 functions to impart elasticity to composite yarn 10 and acts as a scaffolding during and after absorption of the bioabsorbable sheath. Bioabsorbable sheath yarn components 14 and 16 function to provide the composite yarn with relative inelasticity, tensile strength, and absorption characteristics which allow for desirable tissue ingrowth and incorporation of the composite yarn into the body structure. Sheath yarn components 14 and 16 each have a lengthwise axis which is non-perpendicular to the lengthwise axis of core component 12. While core yarn component 12 can be wrapped with a single layer of sheath yarn component, the illustrated arrangement of two layers of sheath yarn components 14 and 16 is generally preferred as this construction helps to give composite yarn 10 a balanced structure which resists crimping or kinking when used in the manufacture of a prosthesis such as shown in FIGS. 5 and 7-11.

Where, as shown in the embodiment of FIG. 1, at least two sheath yarn components are employed in the construction of the composite yarn, the composition, number and denier of the individual filaments, and braiding (if any) of these yarn components as well as their relative rates of bioabsorption can differ. For example, non-absorbable filaments may be combined with absorbable filaments to provide one or more semi-absorbable sheath yarn components. This capability for differential absorption can be advantageously exploited in a connective tissue prosthetic device in which the outermost sheath yarn component is absorbed by the body at a faster rate than the underlying sheath yarn component, or vice versa, thus resulting in a staged absorption of the sheath components of the composite yarn.

Core yarn component 12 must be essentially non-bioabsorbable, i.e., it must resist degradation when, as part of the connective tissue prosthesis of this invention, it is implanted in a body. The term "non-bioabsorbable" as used herein applies to materials which permanently remain within the body or at least remain in the body for a relatively long period of time, e.g., at least about two years. It is preferred to employ a core yarn material which is also elastic, i.e, a polymeric material which in filamentous form exhibits a relatively high degree of reversible extensibility, e.g., an elongation at break of at least about 30 percent, preferably at least about 40 percent and more preferably at least about 50 percent. Fiber-forming polymers which are both non-bioabsorbable and elastic, and as such preferred for use as the core yarn component herein, include fiber-forming polyolefins such as polyethylene homopolymers, polypropylene homopolymers, ethylene propylene copolymers, ethylene propylene terpolymers, etc., fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, polyether-polyester copolymers, and the like. Hytrel (DuPont), a family of copolyester elastomers based on (soft) polyether segments and (hard) polyester segments, and span-

dex, an elastomeric segmented polyurethane, provide especially good results.

Hytrel is manufactured in various commercial grades by DuPont, such as Hytrel 4056, 5526, 5556 and 7246. Hytrel 5556 is especially suitable as the core component 12 of the composite yarn 10 when used to form a vascular graft, while Hytrel 7246 is well-suited for the core component 12 of the composite yarn 10 when used to form a ligament prosthesis or tendon augmentation device.

Several properties of the various Hytrel grades are presented in the table below:

drophilic coatings which are suitable for this purpose include polymeric materials such as the sparingly cross-linked poly(hydroxyethyl methacrylate) hydrogels disclosed in U.S. Pat. Nos. 2,976,576 and 3,220,960; hydrogels based on cross-linked polymers of n-vinyl lactams and alkyl acrylates as disclosed in U.S. Pat. No. 3,532,679; graft copolymers of hydroxyalkyl methacrylate and polyvinylpyrrolidone disclosed in U.S. Pat. No. 3,621,079, and many others.

Fiber-forming materials which are relatively inelastic are suitable for providing the sheath yarn component of composite yarn 10 provided such materials are fairly

	Hytrel Grade No. (Injection Molded at 23° C. for Testing)			
	4056	5526	5556	7246
Hardness in durometer points (ASTM Test No. D2240)	40	55	55	72
Flexural Modulus (ASTM Test No. D790)				
at −40° C. in MPa	155	930	930	2,410
at −40° F. in psi	22,500	135,000	135,000	350,000
at 23° C. in MPa	55	207	207	518
at 73° F. in psi	8,000	30,000	30,000	75,000
at 100° C. in MPa	27	110	110	207
at 212° F. in psi	3,900	16,000	16,000	30,000
ASTM Test No. D638				
(i)Tensile Strength at Break,				
MPa	28.0	40.0	40.0	45.8
psi	4050	5800	5800	6650
(i)Elongation at Break, %	550	500	500	350
(ii)Tensile Stress at 5% Strain,				
MPa	2.4	6.9	6.9	14.0
psi	350	1,000	1,000	2,025
(ii)Tensile Stress at 10% Strain,				
Mpa	3.6	10.3	10.3	20.0
psi	525	1,500	1,500	2,900
Izod Impact (Notched) (ASTM Test No. D256, Method A)				
at −40° C. in J/cm	No Break	No Break	No Break	0.4
at −40° F. in ft-lbf/in	No Break	No Break	No Break	0.8
at 23° C. in J/cm	No Break	No Break	No Break	2.1
at 73° F. in ft-lbf/in.	No Break	No Break	No Break	3.9
Resistance to Flex Cut Growth, Ross (Pierced), in Cycles to 100% cut growth (ASTM. Test No. D1052)	$>1 \times 10^6$	$>5 \times 10^5$	$>5 \times 10^5$	—
(iii)Initial Tear Resistance, Die C (ASTM Test No. D1004),				
in kN/m	101	158	158	200
in lbf/in.	580	900	900	1,146
Melt Flow Rate in g/10 min. (ASTM Test No. D1238)	5.3	18	7.0	12.5
Test Conditions: Temperature, °C./Load, Kg	190/2.16	220/2.16	220/2.16	240/2.16
(iv)Melting Point (ASTM Test No. D3418)				
in °C.	148	202	202	219
in °F.	298	396	396	426
Vicat Softening Point (ASTM Test No. D1525)				
in °C.	108	180	180	207
in °F.	226	356	356	405
Specific Gravity (ASTM Test No. D792)	1.16	1.20	1.20	1.25
Water Absorption, 24 hr. in % (ASTM Test No. D570)	0.6	0.5	0.5	0.3

(i)head speed 50 mm/min. or 2 in/min
(ii)head speed 25 mm/min or 1 in/min.
(iii)specimens 1.9 mm or 0.075 in. thick.
(iv)differential scanning calorimeter (DSC), peak of endotherm

Corresponding properties of other grades of Hytrel are available from DuPont.

If desired, the core yarn component can be provided with a nonabsorbable hydrophilic coating to improve its wettability by body fluids, e.g., synovial fluid. Hy-

rapidly bioabsorbed by the body, e.g., exhibiting a loss of tensile strength in from about 2 to about 26 weeks and total absorption within from about two to about fifty

two weeks. It is to be understood, however, that the expression "relatively inelastic" does not preclude the presence of some minor degree of elasticity in the sheath yarn component, merely that it excludes a degree of elastic behavior as described in connection with the preferred type of core yarn component.

The sheath yarn component can be woven, braided or knitted in whole or in part and will ordinarily possess a relatively high tensile strength, e.g., a straight tensile strength of at least about 30,000 p.s.i., preferably at least about 60,000 p.s.i. and more preferably at least about 90,000 p.s.i.

Bioabsorbable, relatively inelastic fiber-forming polymers and polymer blends from which the sheath yarn component herein can be formed include those derived at least in part from such monomers as glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, e-caprolactone, hydroxycaproic acid, etc., and various combinations of these and related monomers as disclosed, e.g., in U.S. Pat. Nos. 2,668,162; 2,703,316; 2,758,987; 3,225,766; 3,297,033; 3,422,181; 3,531,561; 3,565,077; 3,565,869; 3,620,218; 3,626,948; 3,636,956; 3,736,646; 3,772,420; 3,773,919; 3,792,010; 3,797,499; 3,839,297; 3,867,190; 3,878,284; 3,982,543; 4,047,533; 4,052,988; 4,060,089; 4,137,921; 4,157,437; 4,234,775; 4,237,920; 4,300,565; 4,429,080; 4,441,496; 4,523,591; 4,546,152; 4,559,945; 4,643,191; 4,646,741; 4,653,497; and, 4,741,337; U.K. Patent No. 779,291; D. K. Gilding et al., "Biodegradable polymers for use in surgery—polyglycolide/poly(lactic acid) homo- and copolymers: 1", *Polymer*, Volume 20, pages 1459-1464 (1979), and D. F. Williams (ed.), *Biocompatibility of Clinical Implant Materials*, Vol. II, ch. 9: "Biodegradable Polymers" (1981).

Sheath yarn components manufactured from polymers of high lactide or glycolide content, e.g., those in which at least about 75 percent of the monomeric units are derived from either glycolide or lactide, are preferred for the construction of the composite yarn of this invention. Polymers of high glycolide content tend to be absorbed more quickly than those possessing a high lactide content. Accordingly, the glycolide-based polymers may be preferred for the manufacture of a sheath yarn component providing the outermost sheath yarn(s) in a multiple sheath yarn component construction, the underlying internal sheath yarn(s) being manufactured from the more slowly absorbable lactide-based polymers. An especially preferred lactide-glycolide copolymer for forming the sheath yarn component of the composite yarn contains from about 70 to about 90, and preferably from about 75 to about 85 mole percent lactide monomer with the balance being provided by the glycolide monomer. Thus, for example, a sheath yarn component formed from a lactide-glycolide copolymer based on 80 mole percent lactide-20 mole percent glycolide is especially advantageous for constructing the composite yarn, and ultimately, the connective tissue prosthesis, of the present invention. The sheath yarn component, which is preferably braided around the core yarn component, may comprise a plurality of bioabsorbable fibers in turn comprising at least two different chemical compositions.

The deniers of core yarn component **12** and sheath yarn components **14** and **16** are not especially critical and those of commercially available yarns such as Vicryl (a glycolide/lactide copolymer suture available from Ethicon) and Dexon (a polyglycolide suture available from American Cyanamid) are suitably employed. Preferably, the deniers are selected so as to provide a composite yarn having an overall denier of from about 40 to about 1200 and preferably from about 80 to about 500, the overall denier of the core and/or sheath yarn components being from about 20 to about 600 and preferably from about 40 to about 300. The deniers of individual filaments in the core and sheath yarn components of multifilamentous construction can vary widely, e.g., from about 0.2 to about 6.0 and preferably from about 0.4 to about 3.0. The base weight for a desired composite yarn will determine the size and weight of the component elements of the yarn. Composite yarn **10** possesses sufficient core material to impart, inter alia, a desired resiliency and sufficient sheath material to provide, inter alia, a desired tensile strength for a particular connective tissue prosthetic application. In general, the core component can represent from about 20 to about 80 percent, and preferably from about 30 to about 70 percent of the total weight of composite yarn **10**. Optimum core and sheath component weights will naturally vary depending on the specific application and can be readily determined in a given case based on the desired physical properties of the prosthetic device without undue experimentation.

Methods and apparatus for covering core yarn components with sheath yarn components are well known and need not be described here in detail. In general, the sheath yarn components are wrapped about the core yarn component on a covering machine which includes a hollow spindle with rotating yarn supply bobbins supported thereon. The elastic core yarn component is fed through the hollow spindle and the elastic sheath yarn components are withdrawn from the alternate direction rotating supply bobbins and wrapped about the core yarn component as it emerges from the hollow spindle. The core yarn component is preferably under a slight tension during the covering procedure and the sheath yarn components are laid down in a side-by-side array. The number of wraps per inch will depend on the denier of the sheath yarn components but should be sufficient to cause the sheath yarn components to lay close to the core yarn component when tension on the latter is relaxed.

As desired, the filaments which comprise a sheath yarn component can be provided with no twist or with varying degrees of twist. Where the yarns are twisted, it can be advantageous to balance or equalize the twist in the final composite yarn structure. Thus, for example, in the embodiment of composite yarn **10** in FIG. **1**, if sheath yarn component **14** has a given twist, sheath yarn component **16** should have an equivalent twist. Since sheath yarn components **14** and **16** are laid down in opposite directions, the twist in each of these yarn components will be neutralized in the final structure of the composite yarn. Similarly, sheath yarn components **14** and **16** are advantageously of about equal weight in order to provide further balance in the composite yarn.

The composite yarn **20** shown in FIG. **2** is similar to that of FIG. **1** except that core yarn component **22** constitutes a monofilament and internal and external sheath yarn components **24** and **26**, respectively, each constitutes a monofilament. In all other structural and compositional respects, composite yarn **20** can be like that of composite yarn **10**.

An alternative composite yarn **30** is illustrated in FIGS. **3** and **4**. Composite yarn **30** comprises a core yarn component **33** and a braided sheath yarn component **34**. As with core yarn components **12** and **22** of

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000224

FIGS. 1 and 2, core yarn component 33 is made up of one or more biocompatible, essentially non-bioabsorbable and preferably elastic filaments 36 which define the longitudinal axis of composite yarn 30. Braided sheath yarn component 34 comprises individual sheath yarn filaments or sheath yarn filament bundles 35 which traverse core yarn component 33 in a substantially conventional braided configuration to provide core yarn component 33 with a braided tubular external sheath 34. The individual sheath yarn filaments or sheath yarn filament bundles 35 are biocompatible, bioabsorbable or semi-bioabsorbable, and relatively inelastic. In a preferred embodiment of the present invention as illustrated in FIGS. 3 and 4, sheath yarn component 34 comprises sheath yarn filaments of different chemical composition. For example, a portion of the sheath yarn filaments 35', e.g., 30 to 70% by weight, may be formed of a bioabsorbable polymer exhibiting relatively slow bioabsorption, e.g., polylactide or a copolymer comprising a high lactide mole percentage, while the remainder of the sheath yarn filaments 35" may be formed of a second bioabsorbable polymer which exhibits relatively fast bioabsorption, e.g., polyglycolide or a copolymer comprising a high glycolide mole percentage. Sheath yarn component 34 may also be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable.

In the embodiment illustrated in FIGS. 3 and 4, core yarn component 33 is preferably manufactured from Hytrel filaments 36 and has a denier of about 270, while sheath yarn component 34, which is braided on an eight carrier braider, has a denier of about 204, for a total denier of this composite yarn 30 of about 474.

FIG. 5 illustrates an anterior cruciate ligament prosthesis 37 manufactured from warp and filling composite yarns 10 of FIG. 1. Prosthesis 37 is constructed by constructing a sheath 31 about core 32 by weaving, braiding or knitting on a known or conventional loom. For example, the sheath may be braided about the core on a braiding machine which includes braider bobbins. Composite yarn forming the sheath may be wound onto an appropriate number of braider bobbins which are then loaded onto a carrier braider with the yarns on the bobbins then being braided and tied to form the sheath. The core (if one is required) can be pulled through the sheath, e.g. manually to form the prosthesis. In other words, the core will be at least partially surrounded by the sheath. Other prostheses illustrated herein can be manufactured in similar fashion. The sheath components of the individual composite yarns from which ligament prosthesis 30 is manufactured will erode over time due to their bioabsorption leaving only the nonabsorbable core component as a permanent or long term scaffold for new ligament tissue growth.

FIGS. 7-11 illustrate examples of other ligament prostheses which can be manufactured from the composite yarn of the present invention, e.g. as illustrated in FIGS. 1-3. More particularly, FIG. 7 illustrates a tubular ligament prosthesis or tendon augmentation device 40 having an unbraided center section 41 bounded by braided sections 42 and 43. The individual composite yarns 44 in the unbraided center section 41 can be drawn in generally parallel relationship, if required. The length of the unbraided center section 41 can vary, e.g., from about one or two inches up to about seven or eight inches. The unbraided center section 41 provides tensile strength and/or tissue ingrowth advantages.

Additionally, a tubular ligament prosthesis or tendon augmentation device 45 as illustrated in FIG. 8 can be manufactured from the composite yarn of the present invention. The prosthesis 45 is similar to the one illustrated in FIG. 7 and comprises an unbraided center section 46 bounded by braided sections 47 and 48. A helical wrap 100 is provided about the unbraided center section 46 to improve handling and manipulation of the unbraided section 46 during implantation, while absorption/degradation of the helical wrap 100 frees the individual yarns 49 of the center unbraided section 46 to provide the appropriate tensile strength and/or tissue ingrowth advantages. In this regard, the yarn forming the helical wrap 100 can be the composite yarn of FIGS. 1-3 or formed of a different kind of material, e.g. completely bioabsorbable or nonbioabsorbable material. The tubular ligament prostheses of FIGS. 7 and 8 are both constructed by braiding the end sections 42, 43 or 47, 48 in a known or conventional loom and, in the case of FIG. 8, additionally wrapping the helical yarn 100 about the center unbraided section 46, also with a known or conventional loom. The prostheses of FIGS. 7 and 8 are especially suitable as replacements for anterior cruciate ligaments.

FIG. 9 illustrates a braided prosthesis 70 which can be manufactured from the composite yarns of FIGS. 1-3 and which is also modified along the length thereof. More specifically, the prosthesis of FIG. 9 comprises a center region 50 bordered by first outer regions 51, 52, second outer regions 53, 54, third outer regions 55, 56, fourth outer regions 57, 58, and fifth outer regions 59, 60. The center region 50 comprises a sheath of braided composite yarn, e.g., as illustrated in FIGS. 1-3, about a core (not illustrated) also formed of composite yarn. First outer regions 51, 52 additionally comprise a wrapping 61 about the braided yarn, this wrapping 61 being formed of the same composite yarn as illustrated in FIGS. 1-3 or a different kind of material, e.g. a totally bioabsorbable or nonabsorbable material. This wrapping 61 serves to at least temporarily retain the sheath about the core.

The second outer regions 53, 54 also formed of tubular braided composite yarn as illustrated in FIGS. 1-3 with an appropriate core material (not illustrated) that forms a thicker core than any core present in center section 50 (the center section 50 can be coreless, if required). Third outer regions 55, 56 are divided as illustrated in FIG. 9 to form respective openings 62 and 63. This allows attachment means to be inserted through the respective openings to secure the ligament prosthesis 70 in place. As illustrated in FIG. 9, the sections 55, 56 around the openings 62 and 63 are also covered with wrapping 64 which is similar to the wrapping 61 covering regions 51 and 52.

Next, fourth outer regions 57 and 58 follow which are similar in structure and composition to second outer regions 53 and 54. Regions 57 and 58 narrow down into fifth outer regions 59 and 60 as illustrated in FIG. 9, which can be used, e.g. for threading the ligament prosthesis 70. All sections of prosthesis 70, including the various wrappings 61 and 64, can be fabricated together on a conventional known loom. Prosthesis 70 is especially suitable as a replacement for an anterior cruciate ligament.

FIG. 10 discloses a coreless prosthetic ligament 80 that can be prepared from the composite yarn illustrated in FIGS. 1-3. The coreless prosthetic ligament is braided with a wider central section 81, and a narrower

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000225

outer section from which unwoven yarns 83 extend to form a leading section to enhance threading of prosthetic ligament 80 upon implantation. Sheath yarns 84 of prosthetic ligament 80 can be woven, braided, or knitted on a conventional loom. Sheath sections 81 and 82 of ligament prostheses 80 are tubular, i.e. coreless. Prostheses 80 is also especially suitable as a replacement for an anterior cruciate ligament.

As illustrated in FIG. 11, a ligament prosthesis 90 can be prepared from composite yarns illustrated in Figs. 1-3 of the present invention which form a sheath about a supporting structure (not illustrated). This supporting structure can be a core formed from the composite yarns as described above, or it can be a single, integral member, formed of semi-bioabsorbable or non-bioabsorbable material forming a supporting base for yarns 91. This supporting structure, along with the bundle of yarns 91, can be divided into two branches 90*a* and 90*b*, with the yarns 91 of the prosthesis retained on the supporting structure or core at various points by fastening means 92 which can also be constituted by composite yarn of FIGS. 1-3 or by other kinds of material, e.g. totally bioabsorbable or nonabsorbable filaments. In this regard, the yarns 91 need just be bundled together without any interweaving, braiding or knitting, so long as the yarns 91 are securely held together on the core by the fastening means 92. Alternatively, yarns 92 can be woven, knitted, or braided about the core on a conventional loom to form branches 90*a* and 90*b*.

Other prosthetic structures which can be prepared with the composite yarn of the present invention are apparent to one of skill in the art in light of the disclosure herein.

It is within the scope of this invention to coat or impregnate the prosthesis with, or otherwise apply thereto, one or more materials which enhance its functionality, e.g., surgically useful substances, such as those which accelerate or beneficially modify the healing process when the prosthesis is applied to a graft site. So, for example, the prosthesis can be provided with a therapeutic agent which will be deposited at the grafted site. The therapeutic agent can be chosen for its antimicrobial properties, capability for promoting tissue repair or for specific indications such as thrombosis. Thus, for example, antimicrobial agents such as broad spectrum antibiotics (gentamicin sulphate, erythromycin or derivatized glycopeptides) which are slowly released into the tissue can be incorporated into the prosthesis to aid in combating clinical and sub-clinical infections in a surgical or trauma wound site.

To promote wound repair and/or tissue growth, one or several growth promoting factors can be introduced into the tubular prosthesis, e.g., fibroblast growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor, magainin, and so forth. To decrease abrasion, increase lubricity, etc., the prosthesis can be coated with copolymers of glycolide and lactide and polyethylene oxide, calcium salts such as calcium stearate, compounds of the Pluronic class, copolymers of caprolactone, caprolactone with PEO, polyHEMA, etc. Especially advantageous is a coating of hyaluronic acid with or without cross-linking.

Additionally, polypeptides such as Human Growth Factor (HGF) can also be coated upon or impregnated in the prosthesis to promote healing. The term "Human Growth Factor" or "HGF" embraces those materials, known in the literature, which are referred to as such

and includes their biologically active, closely related derivatives. The HGFs can be derived from naturally occurring sources and are preferably produced by recombinant DNA techniques. Specifically, any of the HGFs which are mitogenically active and as such effective in stimulating, accelerating, potentiating or otherwise enhancing the wound healing process are useful herein, e.g., hEGF (urogastrone), TGF-beta, IGF, PDGD, FGF, etc. These and other useful HGFs and closely related HGF derivatives, methods by which they can be obtained and methods and compositions featuring the use of HGFs to enhance wound healing are variously disclosed, inter alia. in U.S. Pat. Nos. 3,883,497; 3,917,824; 3,948,875; 4,338,397; 4,418,691; 4,528,186, 4,621,052; 4,743,679 and 4,717,717; European Patent Applications 0 046 039; 0 128 733; 0 131 868; 0 136 490; 0 147 178; 0 150 572; 0 177 915 and 0 267 015; PCT International Applications WO 83/04030; WO 85/00369; WO 85/01284 and WO 86/02271 and UK Patent Applications GB 2 092 155 A; 2,162,851 A and GB 2 172 890 A, all of which are incorporated by reference herein. Of the known HGFs, hEGF, TGF-beta and IGF are preferred for use in the therapeutic composition of this invention.

The HGFs can be introduced with appropriate carrier such as carrier proteins disclosed, e.g., in "Carrier Protein-Based Delivery of Protein Pharmaceuticals", a paper of Biogrowth, Inc., Richmond, Calif., presented at a symposium held June 12-14, 1989 in Boston, Mass.

EXAMPLE 1

The following illustrates the manufacture of a ligament prosthesis as illustrated in FIG. 5.

A 420 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn as the core component and a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn providing the sheath component.

Six plies of the 420 denier composite yarn were wound onto 32 braider bobbins. The bobbins were loaded onto a 32 carrier braider to provide braided sheath 31. About one meter of the yarns from the 32 bobbins was pulled manually in parallel to provide a core 32 of 80,640 (420×6 ×32) overall denier. Application of braided sheath 31 also 420×6×32 or 80,640 overall denier resulted in ligament prosthesis 37 possessing an overall denier of 161,280. The stress (force in Newtons)-strain characteristics of prothesis 37 were measured and compared with the stress-strain characteristics of a human anterior cruciate ligament as reported in Noyes et al., *Journal of Bone and Joint Surgery*, Vol. 58-A, No. 8, p. 1074, et seq. (Dec. 1976). As shown in the plotted data of FIG. 6, the stress-strain characteristics of prosthesis 37 (continuous line) closely matched those of the natural tissue (broken line), an altogether remarkable achievement relative to known connective tissue prostheses.

EXAMPLE 2

The following illustrates manufacture of a tendon augmentation device 40 as illustrated in FIG. 7.

A 431 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn to provide the core component 12, a lactide (80 mole percent)—glycolide (20 mole percent) copolymer yarn to provide the inner sheath component 14, and a lactide (10 mole percent)—glycolide (90 mole percent) copolymer yarn to provide the outer sheath component 16.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000226

Six plies of the 431 denier composite yarn were wound onto 16 braider bobbins. The bobbins were loaded onto a 16 carrier braider to provide braided sections 42 and 43. About 70 mm of the yarn from the 16 braider bobbins was braided to form one of sections 42 and 43, and then the braiding was stopped. Then, about 35 mm. of the yarn from the 16 braider bobbins was pulled manually to form the unbraided center section 41, and then braiding was continued for another 70 mm of the yarn to form the other of sections 42 and 43. The resulting tendon augmentation device 40 had a total denier of 41,376 (431×6×16).

The tendon augmentation device 40 was implanted in a canine knee replacing the center third of the patellar tendon. Physical testing was carried out comparing two tendon augmentation devices 40 (TAD-1 and TAD-2) to the center third of the canine patellar tendon (⅓ P.T.) being replaced. More specifically, the stress (force in Newtons) —strain or load-deformation characteristics of devices 40 and the canine patellar tendon were measured and compared with one another.

As shown in the plotted data of FIG. 12, the responses of both tendon augmentation devices 40 (TAD 1 and TAD 2) were very similar to the one third canine patellar tendon. Moreover, tendon augmentation devices 40 (TAD 1 and TAD 2) were generally stronger than the replaced canine patellar tendon which failed when too great a load was applied thereto.

EXAMPLE 3

A composite yarn as illustrated in FIGS. 3 and 4 was fabricated using Hytrel 7246 fibers as the core component 33 and bioabsorbable sheath component fibers 35 of two different chemical compositions: first bioabsorbable fibers 35' fabricated from an 80 mole percent lactide/20 mole percent glycolide copolymer, and second bioabsorbable fibers 35" fabricated from a 10 mole percent lactide/90 mole percent glycolide copolymer. The first bioabsorbable fibers 35' were formed into yarn bundles, each yarn bundle comprising 12 filaments and having a total denier of 24. The second bioabsorbable fibers 35" were also formed into yarn bundles, each yarn bundle comprising 17 filaments and having a total denier of 27.

The composite yarn was formed using three Hytrel yarn bundles, each Hytrel yarn bundle comprising 70 filaments, to form a core component 33 of approximately 270 denier. The braided sheath component 34 was formed around the Hytrel core component 33 using an 8 carrier braider, 4 carriers each of the first and second bioabsorbable yarn bundles. The composite yarn thus formed exhibited a tensile strength of 3.19 grams/denier, and is suitable for use in fabricating a connective tissue prosthesis of the present invention.

What is claimed is:

1. A connective tissue prosthesis comprising:

a) a core made up of a first biocompatible composite yarn extending in a lengthwise direction; and

b) a sheath surrounding the core, said sheath being fabricated from a second biocompatible yarn;

the first composite yarn in said core (a) comprising a non-bioabsorbable core yarn component surrounded by an at least semi-bioabsorbable sheath yarn component.

2. The connective tissue prosthesis of claim 1, wherein the second biocompatible yarn in said sheath (b) comprises a non-bioabsorbable core yarn component

surrounded by an at least semi-bioabsorbable sheath yarn component.

3. The connective tissue prosthesis of claim 2 wherein the sheath yarn component is bioabsorbable.

4. The connective tissue prosthesis of claim 1 exhibiting stress-strain characteristics approximately those of the natural connective tissue replaced or augmented by the prosthesis.

5. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a ligament or tendon prosthesis.

6. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a human anterior cruciate ligament prosthesis.

7. The connective tissue prosthesis of claim 1 in which the core component comprises at least one filament.

8. The connective tissue prosthesis of claim 7 in which the core (a) of the prosthesis comprises multiple composite yarns.

9. The connective tissue prosthesis of claim 7 wherein the core component comprises multiple filaments.

10. The connective tissue prosthesis of claim 1 in which the sheath component comprises at least one filament.

11. The connective tissue prosthesis of claim 10 wherein the sheath yarn component comprises multiple filaments.

12. The connective tissue prosthesis of claim 1 in which the core component is manufactured from at least one polymeric material selected from the group consisting of polyethylene homopolymers, polypropylene homopolymers, ethylene-propylene copolymers, ethylene propylene terpolymers, fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, and polyether-polyester copolymers.

13. The connective tissue prosthesis of claim 1 in which the core component possesses an elongation at break of at least about 30 percent.

14. The connective tissue prosthesis of claim 1 in which the sheath component is an absorbable, relatively inelastic polymeric material derived at least in part from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, e-caprolactone and hydroxycaproic acid.

15. The connective tissue prosthesis of claim 1 in which the sheath component is a lactide-glycolide copolymer.

16. The connective tissue prosthesis of claim 12 in which the sheath component is a lactide-glycolide copolymer containing from about 70 to about 90 mole percent lactide units.

17. The connective tissue prosthesis of claim 16 in which the sheath component is a lactide-glycolide copolymer containing from about 75 to about 85 mole percent lactide units.

18. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially woven.

19. The connective tissue prosthesis of claim 18 wherein the sheath (b) is entirely woven.

20. The connective tissue prosthesis of claim 1 further comprising at least one bioactive substance.

21. The connective tissue prosthesis of claim 1, wherein said sheath component is helically wound about said core component.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000227

22. The connective tissue prosthesis of claim 21, additionally comprising

a second sheath component helically wound about said sheath component in a different direction.

23. The connective tissue prosthesis of claim 22, in which said second sheath component is a lactide-glycolide copolymer.

24. The connective tissue prosthesis of claim 22, wherein said first and second sheath components have different ratios of absorption.

25. The connective tissue prosthesis of claim 1, wherein said sheath component is braided around said core component.

26. The connective tissue prosthesis of claim 25, wherein said sheath component comprises a plurality of bioabsorbable fibers, said fibers comprising at least two different chemical compositions.

27. The connective tissue prosthesis of claim 1, wherein said core (a) and sheath (b) together are branched at discrete locations to form gaps between branches of said prosthesis.

28. The connective tissue prosthesis of claim 27, wherein a yarn is wrapped about said sheath (b) at discrete locations to at least temporarily retain said sheath (b) about said core (a).

29. The connective tissue prosthesis of claim 28, wherein said wrapping yarn comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a at least semi-bioabsorbable sheath yarn component.

30. The connective tissue prosthesis of claim 29 wherein said sheath component of said wrapping yarn is bioabsorbable.

31. The connective tissue prosthesis of claim 1 wherein said sheath yarn component is bioabsorbable.

32. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially braided.

33. The connective tissue prosthesis of claim 32 wherein the sheath (b) is entirely braided.

34. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially knitted.

35. The connective tissue prosthesis of claim 34 wherein the sheath (b) is entirely knitted.

36. A connective tissue prosthesis comprising:

a tubular component fabricated from composite yarn, said yarn comprising a biocompatible, core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

37. The connective tissue prosthesis of claim 36, comprising a center section where said yarn is unbraided and bordered by sections where said yarn is braided.

38. The connective tissue prosthesis of claim 37, additionally comprising

a helical wrap about said unbraided center section.

39. The connective tissue prosthesis of claim 38, wherein said helical wrap is fabricated from composite yarn comprising a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

40. The connective tissue prosthesis of claim 39, wherein said sheath component is bioabsorbable.

41. The connective tissue prosthesis of claim 36, additionally comprising

a threading member attached to an end thereof, said threading member comprising a composite yarn which comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

42. The connective tissue prosthesis of claim 41 wherein said sheath component is bioabsorbable.

43. The connective tissue prosthesis of claim 36 wherein said sheath component is bioabsorbable.

44. Method for manufacturing a connective tissue prosthesis, comprising

forming said connective tissue prosthesis from a first biocompatible composite yarn comprising a non-bioabsorbable core yarn component surrounded by an at least semibioabsorbable sheath yarn component.

45. The method of claim 44, wherein said connective tissue prosthesis comprises a core and a sheath, said core being at least partially surrounded by said sheath.

46. The method of claim 45, wherein said biocompatible composite yarn forms said core.

47. The method of claim 44, wherein said biocompatible composite yarn forms said sheath.

48. The method of claim 44, wherein the sheath is woven about the core.

49. The method of claim 48, wherein

the sheath is braided from braider bobbins loaded onto a carrier braider, and

the core is pulled through the thus-braided sheath.

50. The method of claim 48 wherein the sheath is braided about the core.

51. The method of claim 44 wherein said sheath component is bioabsorbable.

52. The method of claim 44 wherein the sheath is knitted about the core.

53. Method for manufacturing a tubular connective tissue prosthesis, comprising

forming a tubular component from composite yarn comprising a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

54. The method of claim 53 wherein the tubular component is formed by weaving.

55. The method of claim 53 wherein the tubular component is formed by braiding.

56. The method of claim 55, wherein the tubular component is braided from braider bobbins loaded onto a carrier braider.

57. The method of claim 53 wherein the tubular component is formed by knitting.

58. The method of claim 53 wherein the sheath component is bioabsorbable.

* * * * *

HERMES DECLARATION
EXHIBIT 15 – PART 7 OF 8

US005116360A

United States Patent [19]

Pinchuk et al.

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[45] Date of Patent: May 26, 1992

[54] MESH COMPOSITE GRAFT

[75] Inventors: **Leonard Pinchuk; John B. Martin, Jr.**, both of Miami; **Bruce A. Weber**, Pembroke Pines, all of Fla.

[73] Assignee: **Corvita Corporation**, Miami, Fla.

[21] Appl. No.: 634,425

[22] Filed: **Dec. 27, 1990**

[51] **Int. Cl.**[5] **A61F 2/06**

[52] **U.S. Cl.** **623/1**; 623/11; 623/12

[58] **Field of Search** 623/12, 1

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Primary Examiner—David Isabella

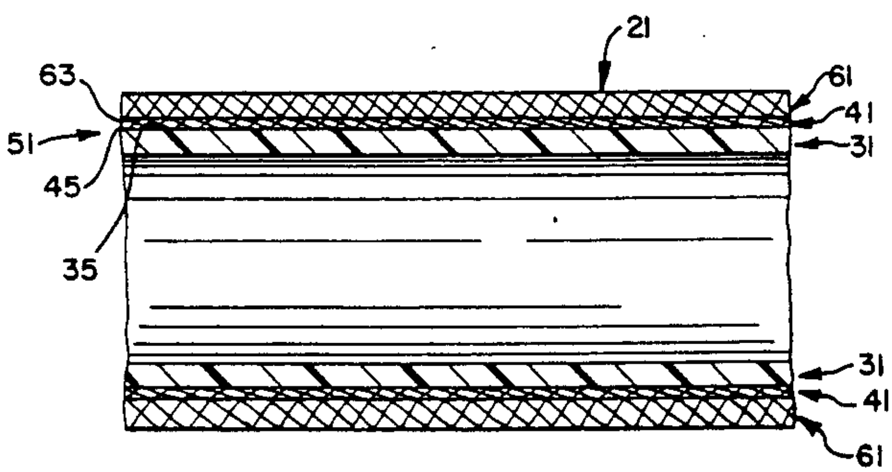
Assistant Examiner—Debra S. Brittingham

Attorney, Agent, or Firm—Lockwood, Alex, FitzGibbon & Cummings

[57] ABSTRACT

A mesh composite graft including an inner component, an outer component formed from strands of durable material, such as polyethylene terephthalate, and an intermediate component made from strands of bicompatible synthetic material having a melting point less than that of the durable material from which the outer component is formed and less than that of the biocompatible synthetic material from which the inner component of the graft is formed. By heating the graft to a temperature grater than the melting point of the material from which the intermediate component is formed but less than the melting point of the outer component material and less than the melting point of the material from which the inner component is formed, the components are bound by the melted intermediate component to provide a totally porous, compliant composite graft reinforced by the outer component.

19 Claims, 1 Drawing Sheet



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000229

FIG. 1

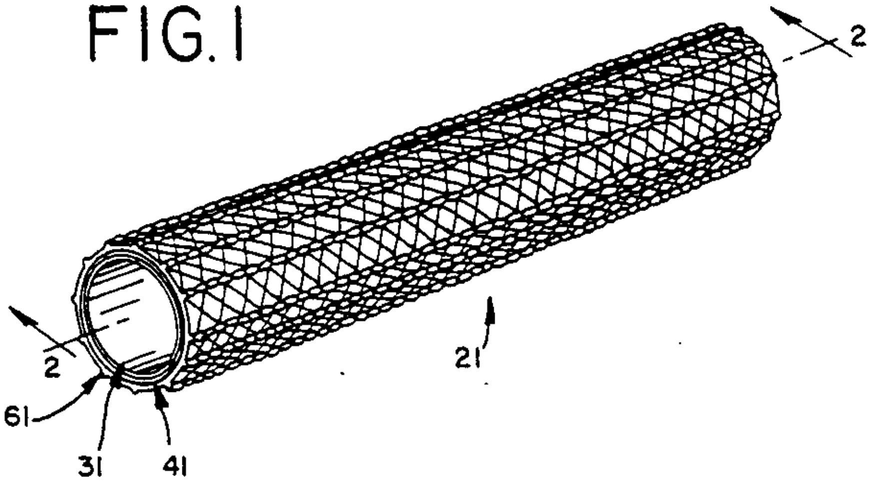
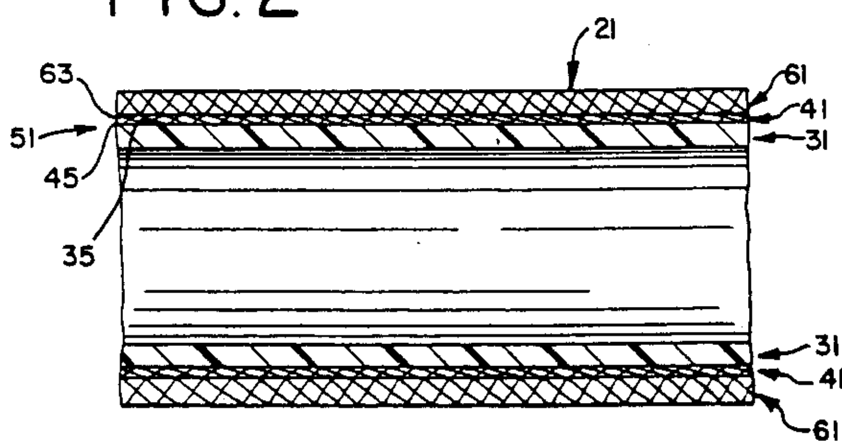


FIG. 2



MESH COMPOSITE GRAFT

BACKGROUND AND DESCRIPTION OF THE INVENTION

The present invention generally relates to implantable prostheses and the like and to methods for making same. More particularly, the invention relates to a graft, such as a vascular graft or AV-shunt, having a compliant porous inner component and a compliant porous load-bearing outer component, bound together by a porous intermediate component that is made of material having a melting point lower than that of the materials from which the inner and outer components are made. With the outer component bound by the intermediate component to the inner component, a porous, yet strengthened integral graft results.

Blood vessels are not straight, rigid tubes but elastic conduits made of a variety of materials and having a compliance that varies with functional considerations. For example, the venous system functions, in part, as the blood reservoir for the body. In order to be able to respond to a larger volume of blood sent into the system because of, for example, a change in arterial blood pressure, the vessels of the venous system must be sufficiently compliant so that they can distend. The arterial system functions as the body's pressure reservoir. In order to avoid the wide swings in the blood pressure and flow that are possible with every contraction and relaxation of the heart, yet be able to maintain sufficient blood pressure so that blood can be pushed into all regions of the body, including through the small-diameter arterioles and the microcirculatory bed, the arteries must have sufficient compliant strength to elastically expand and recoil without the marked distension of the venous system.

Conventional grafts, however, are generally made of materials and in shapes that provide a structure whose compliance is markedly different from that of the walls of the vessel to which they may be attached. Grafts having walls less compliant than that of the host vessel walls are problematic in that conditions, such as intimal hyperplasia and stenotic narrowing, may develop. Grafts with walls having greater compliance than that of the vessel to which the graft is attached are problematic in that a portion of the graft wall may balloon—that is, develop an aneurysm—after implantation.

Other known grafts, while they may be compliant, may not necessarily be made from biocompatible materials. The implantation of a graft made from such material may prompt a thrombogenic or immunological response with the resultant deleterious formation of microthrombi or microocclusions in and around the graft. Other grafts are made from generally non-porous materials, that, accordingly, do not facilitate the ingrowth of cells and tissue within the graft. The full incorporation of the graft into the surrounding host tissue is thereby frustrated. Still other conventional grafts are made from microporous textiles that require preclotting of the vessel wall with blood to prevent leakage of blood at implantation.

A demand therefore is present for an integral graft made from biocompatible materials and having a structure that has compliant strength similar to that of natural tissue but that is sufficiently porous so that the graft may become incorporated into the host tissue yet not leak blood. The present invention satisfies the demand.

The present invention includes a three component system, an inner component, an intermediate component, and an outer component. While the components may be made from materials having generally different melting points and different mechanical properties, at a minimum the inner component and outer component are made from a material or materials having a melting temperature higher than the material from which the intermediate component is made. More specifically, the inner component is porous and is made from a biocompatible synthetic material, preferably a polyurethane composition made with an aromatic polycarbonate intermediate, having a melting point that is, at a minimum, in excess of the melting point of the composition from which the intermediate component is formed (further discussed below).

There are many methods by which the inner component may be made, such as the many known methods used to produce porous compliant vascular prostheses. One such method is termed phase inversion or separation which involves dissolving a urethane in a solvent, such as dimethyl acetamide (DMA), forming a coat on a mandrel—such as by dipping the mandrel into the dissolved urethane—and then immersing the urethane coating in a solution such as water by which DMA may be dissolved, but not urethane, thereby causing the urethane to bead-up and form a porous matrix.

Another method by which the inner component may be formed is termed particle elution. The method utilizes water soluble particles such as salt (NaC1, MgC12, CaCo2, etc.) polymers, such as polyvinylpyrrolidone, sugars etc. The particles are mixed or blended into a urethane composition, and after forming a graft from the mixture such as by dip coating or extruding the particle filled plastic, the particle is eluted out with a suitable solvent.

Additional methods include replamineform, that involves the dissolution of a matrix, such as that of a sea urchin, out of the urethane with hydrochloric acid, spray techniques where filaments or beads of urethane are sprayed onto a mandrel to produce a porous vascular graft, and electrostatic deposition of urethane fibers from solution.

However, the porous vascular graft preferred in this invention is prepared according to the method detailed in U.S. Pat. No. 4,475,972 to Wong. This patent is incorporated hereinto by reference. An antioxidant may be added to further prevent degradation of the fibers drawn of the material from which the inner component is made.

Regardless of the nature and method of manufacturing the porous inner component, the intermediate component is comprised of one or more layers of a biocompatible synthetic material, preferably a polyurethane material, having a melting point lower than the melting point of the material from which the inner component is formed and lower than the melting point of the material from which the outer component is made.

The outer component comprises a mesh network made of strands, fibers, beads or expanded versions of a durable material such as a composition of fluorocarbons, such as expanded polytetrafluoroethylene ("ePTFE")—commonly termed Teflon—or stable polyesters, such as preferably polyethylene terephthalate ("PET")—commonly termed Dacron. This material is preferably warp-knitted in a tricot or double tricot pattern and shaped in a tubular configuration. It can also be appreciated that the outer component can be woven, braided,

weft-knitted and the like with loose fibers, textured fibers and the like to provide increased compliance. With the three components in place, a composite graft according to the present invention is formed by heating the structure to a temperature at or above the melting point of the material from which the intermediate component is formed but below the melting temperature or temperatures of the material from which the outer component is formed and of the material from which the inner component is formed. In this temperature range, the intermediate component may melt without the melting of either the inner component and the outer component, thereby mechanically bonding the inner component to the outer component.

The multi-component system of the present invention provides a number of advantages over conventional grafts. The use of a durable material, such as PET or ePTFE, from which the outer component may be formed is advantageous because of the known strength that such material has in the body. Devices made from PET or ePTFE when implanted in the body are known to maintain their integrity for some three decades. Further advantageously, it has been found that a graft—made according to the present invention and in which PET is used to form the outer component —has a burst strength and a tensile strength that is some two times greater than that of a conventional graft. Such strength prevents the dilation of the vessel in response to, for example, an increase in blood flow and/or pressure, creep relaxation of the urethane, biodegradation of the urethane, plasticization of the urethane, etc. Decreases in the strength of PET that may occur after implantation due, for example, to the absorption of water after implantation, are minimal as Dacron has a low water absorption ability.

The use of a knitted pattern according to which the durable strands of the outer component may be configured is advantageous due to the increased compliance such a pattern provides. As stated above, a durable material such as PET is recognized as a strong yet not necessarily compliant material. However, by knitting the strands from which the outer component is formed into a network, a compliant reinforcing outer component is formed. The use of such a material from which to form the outer component in the three component system of the present invention advantageously provides a strengthened, yet compliant graft.

The winding of strands of synthetic material, such as polyurethane over a mandrel to form an inner component is further advantageous because of the resultant porosity of the component. While the intermediate component may be made porous, for example, by painting synthetic material over the inner component and utilizing the phase inversion method or the particle elution method to form a porous matrix, preferably the intermediate component is formed by winding strands of synthetic material, such as polyurethane over the inner component, to provide a highly porous network. Utilizing strands of PET configured in a knitted pattern to form the outer reinforcement component further provides a porous network. Advantageously, by combining these individually porous components together in a composite graft, a totally porous integral graft results. Porosity is an advantage in medical devices, such as vascular grafts, because an open structure allows vascular fluid to infiltrate and communicate to and from the surrounding tissue and the interior of the graft and allows the ingrowth of tissue to occur within the

graft. Accordingly, the device becomes better incorporated into the surrounding tissue, thereby further securing the device within the implantation site.

Uniting the three components into a single composite graft advantageously facilitates the use of the device. The graft may be implanted without the need for any assembly immediately prior to use. The graft may be also cut and/or sutured as a unit without the need for the separate cutting and/or suturing of each component. Methods for cutting the composite graft include scalpel, scissors, hot wires, shaped blades, and the like. The speed with which the graft may be implanted is a particularly distinct advantage since the device is implanted only when a patient is undergoing surgery.

The use of a polycarbonate intermediate rather than, for example, a polyether urethane to make the polyurethane material from which the inner component is preferably made is advantageous as the resultant inner component better resists degradation. The resistance to degradation is further aided by the addition of antioxidant to the material from which the inner component is formed.

It is, accordingly, a general object of the present invention to provide an improved graft.

Another object of the present invention is to provide an integral improved graft made from a composite of layers of synthetic materials.

It is also an object of the present invention to provide a graft that is totally porous thereby facilitating the incorporation of the graft into the site of implantation.

An additional object of the present invention is to provide an improved graft having an outer component which strengthens the device without significantly impairing the overall compliance of the graft.

These and other objects, features and advantages of this invention will be clearly understood and explained with reference to the accompanying drawings and through a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

In the course of this description, reference will be made to the attached drawings, wherein:

FIG. 1 is a perspective view illustrating an embodiment of a composite vascular graft according to the present invention with an outer component of knitted durable material positioned over and bound by an intermediate component to an inner component; and

FIG. 2 is a cross sectional view of the composite vascular graft according to the present invention illustrated in FIG. 1.

DESCRIPTION OF THE PARTICULAR EMBODIMENTS

The present invention is a composite vascular graft—generally designated as 21 in FIGS. 1 and 2—comprised of an inner component 31, an intermediate component 41, and an outer component 61. The inner component will be described first.

Inner component 31 is fabricated from a biocompatible synthetic material, preferably polyurethane, having a melting temperature that is, at a minimum, greater than the melting temperature of the material from which the intermediate component is formed. Preferably, in those embodiments in which the inner component 31 is formed from polyurethane, it is made with an aromatic polycarbonate urethane. Polycarbonate urethanes are preferred over polyether urethanes due to

their superior biostability. The aromatic polycarbonate urethanes have melting points in the range of 150° C. to 230° C. This is in contrast to some aliphatic polycarbonate urethanes that have melting points between 90° C. and 130° C. It can also be appreciated that the inner member may be composed of non-urethane materials such as silicone rubber, polyolefins, fluoroelastomers, ePTFE, and the like. An antioxidant, such as Irganox 1010, may be added to the inner member to further prevent degradation of the strands from which the inner component is formed. The melting temperature of the material from which the inner component is preferably formed exceeds 150° C.

The methods by which the inner component 31 may be fabricated include those disclosed in U.S. Pat. No. 4,475,972 to Wong. According to a fabrication method taught in the Wong patent, termed "solution processing", the inner component material is dissolved in a solvent and forced out of one or more orifices to form one or more continuous fibers. The fibers are drawn directly onto a rotating mandrel. As the distributor or spinnerette reciprocates along the mandrel, non-woven strands are layered on top of each other to form porous, non-woven network of criss-crossing strands.

The intermediate layer 41 is formed of a biocompatible synthetic material, such as a polyolefin, a silicone thermoplastic material, etc., or preferably a polyurethane material having a melting temperature less than that of the materials from which the inner and outer components are formed. The intermediate layer can be drawn in the manner described in the Wong patent so that at least one fibrous layer is laid over the inner component 31 to form a porous intermediate layer. This intermediate layer can be spun from solution as described in the Wong patent or can be simply wound onto the inner layer from a spool of the biocompatible low melting point material. Alternatively, phase inversion or particle elution methods may be used to form a porous intermediate component. Examples of suitable low melting point biocompatible materials include the aliphatic polycarbonate or polyether urethanes with melting points of 90° C. to 130° C. The resultant porous, non-woven network of strands forming the intermediate component 41, as drawn over the inner component 31 form a unit 51 which facilitates the transmission of fluid.

Mesh 61, composed of strands of durable material, such as PET or ePFTE , knitted or woven in a generally elongated cylindrical shape and whose inner surface 63 is of a diameter equal to or slightly larger than the diameter of the outer surface 45 of the intermediate component 41, is fitted over the intermediate component 41. To provide compliance to the mesh network of strands from which the outer component is formed, the strands are configured preferably in a knitted pattern. Tricot or double tricot warp knit patterns are preferred. Double tricot patterns are further advantageous because they provide greater depth to the outer component 61 and thereby facilitate the acceptance of and retention of sutures and tissue ingrowth through the graft 21. Tricot or double tricot warp patterns are further advantageous in that they are generally more interlocking than other patterns and therefore resist "running". Other acceptable patterns according to which the strands of the outer component 61 may be formed include jersey or double jersey patterns, woven or braided and multiple layers of the above. Also, the fibers comprising the outer structure may be textured or non-textured and be of a variety of deniers.

The outer component 61 as positioned over the inner component and intermediate component is heated to a temperature equal to or greater than the temperature at which the material from which the intermediate component 41 is formed melts but less than the temperature and/or temperatures at which the material or materials from which the outer component and from which the inner component 31 is formed melts. When the inner component 31 is formed from the preferred material described above, the components are heated to a temperature less than 150° C. but greater than the temperature at which the material from which the intermediate component 41 is formed melts, such as 110° C. By maintaining the three components at such a temperature for a period of time, such as ten minutes, the intermediate component melts thereby securing the outer component 61 and the inner component 31 to each other. To further ensure the secure full engagement of the outer component 61 by the melted intermediate component 41, the outer component 61 may be forcefully pressed into the intermediate component 41 during the heating step such as mechanically and/or with or under pressure. After heating, the united three components are cooled thereby providing an integral mesh composite graft 21.

A mesh composite graft 21 according to the present invention is totally porous and compliant, yet advantageously includes a load bearing component, the outer component 61, which adds strength to the graft and prevents the failure of the graft even in response to greater fluid volume pressures from within, creep relaxation of the inner member and possible biodegradation effects of the inner member.

The advantageous compliance of the composite graft may be adjusted by varying the number of strands from which the inner component and the intermediate component 41 are formed. The compliance of the composite graft 21 may be adjusted also by varying the materials from which the inner component 31 and the intermediate component 41 are formed while maintaining the relationship that the intermediate component 41 must melt at a lower temperature than the materials from which the outer component and the material from which inner component 31 is formed. The compliance of the mesh composite graft 21 may be adjusted further by adjusting the angle at which the strands of the inner component 31 and/or the strands of the outer component 61 are laid down—a higher angle provides a less compliant component and thereby a less compliant graft.

The compliance may be adjusted even further by altering the knitting parameters, such as courses and wales per inch, the stitch density, the fiber denier, the number of strands per filament, the composition of the fibers and filaments such as a mixture of PET and Spandex compositions and whether the outer member is knitted, woven or braided.

The advantageous overall porosity of the graft 21 may be adjusted also in a number of ways. In addition to varying the size and number of the strands from which the inner component 31 and intermediate component 41 are formed, the strands of each component may be drawn at different angles to provide decreased pore size and resultant decreased porosity. Similarly, the porosity of the outer component 61, and thereby the porosity of the composite graft 21 may be varied by varying the

size and/or number of the strands and stitch density used to make the outer component mesh.

It can also be appreciated that the outer component need not be a tube formed specifically for this purpose from materials as above but can also be made from a vascular graft preformed from a porous matrix material such as ePTFE. One such graft is manufactured by W. L. Gore and marketed as a Gore-Tex graft. The ePTFE graft may be sheathed over the previously described inner and intermediate components and heat fused into a similar composite graft described in this document. Similarly, the inner members may be a Gore-Tex graft, the intermediate component, a heat fusable thermoplastic, and the outer component, a Dacron knit.

Regardless of the configuration of the inner, intermediate and outer components of the graft, i.e. be it spun, salt eluted, phase inverted, wound with an outer PET mesh, or in which an ePTFE configuration is utilized, the resultant composite graft 21 as formed may be implanted in vascular locations and retained in place through conventional methods, such as suturing. The preferred use of PET, knitted in a preferred tricot or double tricot pattern, from which to make the outer component 61 of the graft 21 provides a graft having a greater thickness than grafts without such a load bearing component. The outer component 61 facilitates the greater retention of the sutures within the graft.

It will be understood that the embodiments of the present invention as described are illustrative of some of the applications of the principles of the present invention. Modifications may be made by those skilled in the art without departure from the spirit and scope of the invention.

We claim:

1. A composite graft for implantation within a host, comprising:

an inner component made from wound, criss-crossing layers of fibers of a first biocompatible synthetic material and shaped to form a porous generally elongated cylindrical shape having a lumen through which blood may flow, said inner component having an outer surface;

an intermediate compliant bonding component made from wound, criss-crossing layers of fiber of a second biocompatible synthetic material, said second material having a melting point lower than the melting point of said first material and lower than the melting point of polyethylene terephthalate, said intermediate component positioned generally over and substantially covering said outer surface of said inner component, said intermediate component being porous and having an outer surface;

said intermediate component as positioned over said outer surface of the inner component forming a fluid transmission unit;

an outer component made from a mesh formed from strands of matrices of durable material, said strands or matrices preformed in a generally elongated cylindrical shape having a lumen therethrough and a diameter which is approximately equal to the outside diameter of said intermediate component, said outer component is positioned over and substantially covering said outer surface of the intermediate component; wherein each said outer component and said inner component is bonded to said intermediate component when each of the components is heated to a temperature less than the melting temperature of said firs material and said durable material thereby securing said components to each other to form a totally porous mesh composition graft.

2. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is polyurethane.

3. The mesh composite graft according to claim 2, wherein said polyurethane is made with a polycarbonate intermediate.

4. The mesh composite graft according to claim 2, wherein said polyurethane is made with an aromatic polycarbonate urethane.

5. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is silicone rubber.

6. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a polyolefin.

7. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a fluoroelastomer.

8. The mesh composite graft according to claim 3, wherein said polyurethane includes an antioxidant to prevent degradation of said inner component.

9. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is polyurethane.

10. The mesh composite graft according to claim 9, wherein said polyurethane is an aliphatic polycarbonate.

11. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a polyolefin.

12. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a silicon thermoplastic material.

13. The mesh composite graft according to claim 1, wherein said outer component is further secured to said fluid transmission unit by pressing said outer component into said intermediate component during heating.

14. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate.

15. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a tricot pattern.

16. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a double tricot pattern.

17. The mesh composite graft according to claim 2, wherein said mesh is formed from strands of expanded polytetrafluoroethylene.

18. The mesh composite graft according to claim 2, wherein said mesh is preformed from strands of polytetrafluoroethylene.

19. The mesh composite graft according to claim 2, wherein said mesh is a preformed porous matrix of expanded polytetrafluoroethylene.

* * * * *

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 2, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

December 2, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

The braided suture is made up of multifilament yarns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be bundled to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The <u>only</u> component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the essence of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches randomized braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a structured braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,

Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2794
December 2, 1992

Case Docket No.: ETH-782

In re application of Alastair W. Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

MAIL ROOM DEC 4 1992 PAT. & TRADEMARK OFFICE

RECEIVED DEC 10 1992 GROUP 1500

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

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CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 24	minus	** 24	= 0	x $22	= $ 000.00
INDEP. CLAIMS	* 1	minus	*** 3	= 0	x $74	= $ 000.00
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ 000.00

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
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Matthew S. Goodwin
Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

Case Docket No.: ETH-782

In re Application of Alastair W. Hunter et al.

Serial No.: 07/838,511

Filed: February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

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CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 24	minus	** 24	= 0	x $22	= $ 000.00
INDEP. CLAIMS	* 1	minus	*** 3	= 0	x $74	= $ 000.00
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ 000.00

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Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
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For STERILIZED HETEROGENEOUS BRAIDS

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CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 24	minus	** 24	= 0	x $22	= $ 000.00
INDEP. CLAIMS	* 1	minus	*** 3	= 0	x $74	= $ 000.00
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ 000.00

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Charge $ 000.00 to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[ ] A check in the amount of $ ________ is attached.

Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000245

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER A	ETH-782

EXAMINER
RAIMUND,C

15N1

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

ART UNIT	PAPER NUMBER
1504	7

DATE MAILED: 03/18/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on Dec. 2, 1992 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ______

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.

   Of the above, claims 1 - 20 are withdrawn from consideration.

2. ☐ Claims ______ have been cancelled.
3. ☐ Claims ______ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims ______ are objected to.
6. ☐ Claims ______ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ______. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ______ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on ______, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ______; filed on ______.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000246

EXAMINER'S ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 21 is rejected under 35 U.S.C. § 102(e) as being anticipated by Kaplan et al.

Kaplan et al. discloses a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn component. The braided sheath comprises braided filaments or braided filament bundles (column 9, lines 4-12). A sheath component containing filaments of different chemical compositions is specifically disclosed (column 9, lines 12-16). Claim 21 is therefore anticipated by Kaplan et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as

> prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al.

Doddi et al. disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56). Suitable biocompatible, non absorbable filaments include PET and PTFE (column 9, lines 51-53).

Kaplan et al. discloses a ligament prosthesis comprising a core component and a braided sheath component. The core component is "made up of one or more biocompatible, essentially non-bioabsorbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated from one or more non-bioabsorbable fibers (column 9, lines 25-28). It would have been obvious to form the sheath component of the device of Kaplan et al. from PTFE and PET. PTFE is known to inpart improved knot run down properties to sutures (see Block U.S. Pat. No. 3,527,650). PET is noted for its low cost and high strength. The core yarn component must be non-bioabsorbable (column 4, lines 45-46). Since PET is non-bioabsorbable, biocompatible and has the desirable properties noted above, its use as the core component would have been obvious. Claims 21 and 22 are therefore unpatentable over Doddi et al. taken

with Kaplan et al.

Kaplan et al. fail to disclose the prosthesis of their invention connected to a needle. Prosthesis are, however, implanted in the body using a needle. Claims 23 and 24 are therefore unpatentable over Doddi et al. taken with Kaplan et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-2374.

C. Raimund:pdw
February 25, 1993

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

ETH-782

AHH 9/8/93

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Submitted herewith on Form PTO-1449, is a listing of documents known to the Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. §1.56. Copies of these documents are also being submitted.

These documents are being submitted after the first Office Action. Accordingly, the Patent and Trademark Office is authorized to charge Account No. 10-750/ETH-782/HBW the appropriate fee under 37 C.F.R. §1.17(p) for the citation of these documents. Three copies of this statment are included.

CS14107 09/08/93 07838511 10-0750 140 126 200.00CH

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal Brent Woodrow

Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

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August 4, 1993
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Submitted herewith on Form PTO-1449, is a listing of documents known to the Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. §1.56. Copies of these documents are also being submitted.

These documents are being submitted after the first Office Action. Accordingly, the Patent and Trademark Office is authorized to charge Account No. 10-750/ETH-782/HBW the appropriate fee under 37 C.F.R. §1.17(p) for the citation of these documents. Three copies of this statment are included.

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal Brent Woodrow

Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

Sheet 1 of 1

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Docket No. ETH-782	Serial No 838,511
	Applicant Alastair W. Hunter, et al.	
	Filing Date Feb. 19, 1992	Group Art Unit 1504

U.S. PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Name	Class	Sub Class	File Date
CWR	3,463,158	8/26/69	Edward Emil Schmitt, et al.	606	228	1/9/67
CWR	4,979,956	12/25/90	Thomas A. Silvestrini	623	13	7/10/89
CWR	3,636,956	1/25/72	Allan K. Schneider	128	335.5	5/13/70
CWR	4,141,087	2/27/79	Shalaby W. Shalaby, et al.	3	1	1/19/77
CWR	4,959,069	9/25/90	Karl W. Brennan, et al.	606	228	10/20/89

FOREIGN PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Country	Class	Sub Class	Translate Yes	No
CWR	GB 2 082 213	8/16/80	Great Britian	—	—	✓	

OTHER REFERENCES (include author, title, date, pertinent pages, etc.)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000254

Examiner	Date Considered
[signature]	NOVEMBER 8, 1993

Examiner: Initial if citation considered, whether or not citation is in confirmance with MPEP §609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

AUG 9 1993 PAT. & TRADE MARK OFF.

DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#9/Assoc PoA 9/9/93

Applicants:	Alastair W. Hunter, et al.		
Serial No.:	838,511	Art Unit:	1504
Filed :	February 19, 1992	Examiner:	C. Raimund
For :	STERILIZED HETEROGENEOUS BRAIDS		

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

ASSOCIATE POWER OF ATTORNEY

Sir:

In the matter of the above-identified application, I hereby appoint Hal Woodrow (Reg. No.32,501), whose postal address is One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003, my associate attorney to prosecute said application, to make alterations and amendments therein, to file continuing applications claiming the benefit of said application, to receive the patent and to transact all business in the Patent Office connected with said application.

I request all communications with respect to said application be addressed to Audley A. Ciamporcero, Jr., One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003. All telephone calls should be directed to Hal Woodrow at (908) 524-2976.

Signed at New Brunswick, in the County of Middlesex and State of New Jersey, this 3rd day of August, 1993.

Jason Lipow

Attorney for Applicant(s)
Jason Lipow Reg. No. 25509

One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATED: August 3, 1993

MAIL AUG 9 1993 PAT. & TRADEMARK

DOCKET NO. ETH-782 (4)154

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

SEP 1 1993

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated March 18, 1993 for two (2) month(s) from June 18, 1993 to August 18, 1993. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-750/ETH-782/HBW in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

P 30003 08/30/93 07838511 10-0750 030 116 360.00CH

Respectfully submitted,

Hal Brent Woodrow
Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000256

DOCKET NO. ETH-782

AUG 9 1993

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

SEP 1 1993

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

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Please charge Deposit Account No. 10-750/ETH-782/HBW in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

Hal Brent Woodrow
Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993

AUG 9 1993

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.

SEP 1 1993

IN THE CLAIMS

Please amend claim 21 as follows:

(Once Amended)

1 ~~21~~. A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

26

CLAIM 2

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000258

REMARKS

Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amend to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting PET, nylon and aramid materials. Support for there amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yearn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddi et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddi is a significant contribution to the art, Doddi does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

from the group consisting of PTFE, FEP, PFA PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal Brent Woodrow

Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 31 1995

GP 1504

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

November 9, 1993
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

November 9, 1993
(Date of Signature)

11-24-93
7560
Raimund

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

SUPPLEMENTAL AMENDMENT

Dear Sir:

This Supplemental Amendment is an amendment to the Amendment submitted on August 4, 1993.

REMARKS

Applicants have noticed that the Amendment of August 4, 1993 under the heading "In The Claims" states, "Please amend claim 2 as follows:", however, the claim designated as being amended is claim

Noted - corrected by Examiner -
M Lorenzo (SPE)
12-30-93

USSN 838,511

21. Applicants respectfully request this sentence be changed to read "Please amend claim 21 as follows:".

H. Brent Woodrow

Hal Brent Woodrow
Reg. No. 32,501
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 9, 1993

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/[illegible],51[illegible]	[illegible]	HUNTER	[illegible]

15N1/11.3

EXAMINER

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933 7003

ART UNIT	PAPER NUMBER
	11

DATE MAILED:

NOTICE OF ALLOWABILITY

PART I.

1. ☑ This communication is responsive to the Amendment filed August 9, 1993.
2. ☑ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☑ The allowed claims are 21, 23, 24, 7, 8, 10-12, 14, 18-20.
4. ☐ The drawings filed on ______ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] been received. [_] not been received. [_] been filed in parent application Serial No. ______, filed on ______.
6. ☑ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☑ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
   a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. ______. CORRECTION IS REQUIRED.
   b. ☐ The proposed drawing correction filed on ______ has been approved by the examiner. CORRECTION IS REQUIRED.
   c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
   d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:
- ✓ Examiner's Amendment
- _ Examiner Interview Summary Record, PTOL-413
- _ Reasons for Allowance
- _ Notice of References Cited, PTO-892
- ✓ Information Disclosure Citation, PTO-1449
- _ Notice of Informal Application, PTO-152
- _ Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsmen
- _ Other

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000264

Serial Number: 07/838,511

Art Unit: 1504

Part III EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Hal B. Woodrow on November 15, 1993.

Permission was given to amend the claims as follows:

Cancel claims 1, 6, 9, 13, 15, 16, 17 and 22.

In claims 7, 8, 10, 11, 12, 14, 18, 19 and 20, line 1, change "heterogeneous braid" to "surgical suture".

In claim 7, line 1, change "6" to "21".

In claim 10, line 1, change "9" to "8".

In claim 14, line 1, change "13" to "12".

In claim 18, line 1, change "17" to "14".

In claim 20, line 1, change "1" to "21".

In claim 24, line 1, change "22" to "14".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Raimund whose telephone number is (703) 308-2374.

Chris Raimund/cwr
November 15, 1993

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

15N1/111.

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

☐ Note attached communication from the Examiner
☐ This notice is issued in view of applicant's communication filed ____________

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT		DATE MAILED
07/008,511	01/19/93	012	RAYMOND, [illegible]	1301	11/16/[illegible]

First Named Applicant: HUNTER, ALASTAIR W.

TITLE OF INVENTION: STERILIZED HETEROGENEOUS BRAIDS

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	ETH-732	606-231.000	S67	UTILITY	NO	$[illegible]	[illegible]

THE FEE DUE IS THE AMOUNT IN EFFECT AT THIS TIME. IF THE AMOUNT OF THE ISSUE FEE INCREASES PRIOR TO PAYMENT, APPLICANT WILL BE NOTIFIED OF THE BALANCE OF ISSUE FEE DUE.

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.

PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY Status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or

B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or

B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date) and serial number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

B

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advances orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block below, or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**

1 CORRESPONDENCE ADDRESS	2 INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
MAIL ROOM 68 FEB 18 1994 PAT. & TRADEMARK OFF.	INVENTOR'S NAME
JOHNSON PLAZA	Street Address
	City, State and ZIP Code
	CO-INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	[ ] Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
[illegible]	[illegible]	6	[illegible]	[illegible]

First Named Applicant [illegible] 2/18/94

TITLE OF INVENTION [illegible]

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
ETH-78?	606-231.000	567	UTILITY	NO	[illegible]	[illegible]

3. Correspondence address change (Complete only if there is a change)

30431 02/22/94 07838511
P.30432 02/22/94 07838511
10-0750 170.00CH
10-0750 30.00CA

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1 Hal Brent Woodrow
2

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: Ethicon, Inc. Recorded- 2/19/92 Reel-6023 Frame-941

(2) ADDRESS: (CITY & STATE OR COUNTRY) Somerville, N.J.

(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION Ohio

A. ☐ This application is NOT assigned.
☒ Assignment is being previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☐ Issue Fee ☐ Advanced Order - # of Copies ____ (Minimum of 10)

6b. The following fees should be charged to: DEPOSIT ACCOUNT NUMBER 10-0750 (ENCLOSED PART C)
XX Issue Fee XX Advanced Order - # of Copies 10 (Minimum of 10)
☐ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Signature of party in interest of record) (Date)
32,501 Hal Brent Woodrow 2/16/94

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

PTOL-85B (REV.7-92)(OMB Clearance is pending)

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Washington, D.C. 20231

94 FEB 18 PM 8:55
PATENT & TRADEMARK OFC
IRSB DIVISION

on February 16, 1994
(Date)

Hal Brent Woodrow
(Signature)

Hal Brent Woodrow
(Typed or Printed Name)

February 16, 1994
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

This form is estimated to take 20 minutes to Complete. Time will vary depending upon the needs of the individual applicant. Any comments on the amount of time you require to complete this form should be sent to the Office of Management and Organization, Patent and Trademark Office, Washington, D.C. 20231 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advances orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**

1. CORRESPONDENCE ADDRESS

MAIL ROOM 68 FEB 18 1994 PAT. & TRADEMARK OFF.

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK NJ 08933-7003

2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
INVENTOR'S NAME
Street Address
City, State and ZIP Code
CO-INVENTOR'S NAME
Street Address
City, State and ZIP Code
☐ Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/[illegible]	[illegible]	[illegible]	[illegible] 3503	11/10/93

First Named Applicant: [illegible]

TITLE OF INVENTION: [illegible] HOMOGENEOUS BEARING [illegible]

Dennis [illegible] 2/18/94

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
	ETH-782	606-232.000	50	UTILITY	NO	$1170.00	02/10/94

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3. Correspondence address change (Complete only if there is a change)

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1 Hal Brent Woodrow
2
3

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)
(1) NAME OF ASSIGNEE: Ethicon, Inc. Recorded- 2/19/92 Reel-6023 Frame-941
(2) ADDRESS: (CITY & STATE OR COUNTRY) Somerville, N.J.
(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION Ohio

A.☐ This application is NOT assigned.
☒ Assignment is being previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☐ Issue Fee ☐ Advanced Order - # of Copies ____ (Minimum of 10)

6b. The following fees should be changed to: DEPOSIT ACCOUNT NUMBER 10-0750
(ENCLOSED PART C)
XX Issue Fee XXX Advanced Order - # of Copies 10 (Minimum of 10)
☐ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Signature of party in interest of record) (Date)
32,501 Hal Brent Woodrow 2/16/94

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

PTOL-85B (REV.7-92)(OMB Clearance is pending)

Certificate of Mailing

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Commissioner of Patents and Trademarks
Washington, D.C. 20231

on February 16, 1994
(Date)

Hal Brent Woodrow
(Signature)

Hal Brent Woodrow
(Typed or Printed Name)

February 16, 1994
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000270

This form is estimated to take 20 minutes to Complete. Time will vary depending upon the needs of the individual applicant. Any comments on the amount of time you require to complete this form should be sent to the Office of Management and Organization, Patent and Trademark Office, Washington, D.C. 20231, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

32,501 Hal Brent Woodrow 2/16/94

REVERSE PTOL-85B (REV. 7-92) (OMB Clearance is pending)

8/1504

ETH: 782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alastair W. Hunter, Dennis D. Jamiolkowski and Arthur Taylor, Jr.

Serial No. 07/838,511 Group No. 1504

Filed: February 19, 1992 Examiner: C. Raimund

For: STERILIZED HETEROGENOUS BRAIDS

CERTIFICATE OF MAILING (37 CFR 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Hal Brent Woodrow
Name of Person Mailing Paper

Date: November 22, 1993 Hal Brent Woodrow
Signature of Person Mailing Paper

12-6-93
7560
Raimund

Commissioner of Patents and Trademarks
Washington, D. C. 20231

AMENDMENT, PETITION AND FEE DELETING CORRECTLY NAMED ORIGINAL PERSON(S) WHO ARE NOT INVENTOR(S) OF INVENTION NOW BEING CLAIMED (37 CFR 1.48(b)

1. This amendment and petition under 37 CFR 1.48(b) is to delete the name(s) of the following person(s) originally named as inventor(s) of the invention now being claimed:

Dennis D. Jamiolkowski

2. Claims Now On File

The claims in this application are as follows:

OK to enter MA

[ ] originally filed claim(s) ______________

[ ] originally filed claims ______________ as amended on ______________

[ ] claim(s) __________ filed on ______________

[X] claim(s) 21-24 filed on February 19, 1992 as amended on August 4, 1993 and amended by the Examiner's Amendment of November 15, 1993

P 30079 12/07/93 07838511 10-0750 1 0 179 170.00CH

USSN 07/838,511

[X] claims 25-33 added by the Examiner's Amendment of November 15, 1993

3. **DILIGENCE**

This amendment and petition is being filed

[X] diligently after discovery that any claim(s) for which the above-named inventor who is being deleted are now no longer the inventor of the subject matter being claimed.

4. **STATUS OF INVENTORSHIP AFTER AMENDMENT**

[ ] Attached is an explanation of the facts, including the ownership of all the claim(s) at the time the last claimed invention was made (Declaration of Inventorship and Common Ownership of Claims in Application).

5. **FEE (37 CFR 1.17(h)**

The fee required is paid as follow:

[X] charge Account No. 10-750/HBW/ETH-782 for any fee deficiency

[X] charge Account No. 10-750/HBW/ETH-782 the sum of $130.00

Hal Brent Woodrow

Hal Brent Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 22, 1993

PTO UTILITY GRANT

Paper Number 14

The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person or persons having title to this patent the right to exclude others from making, using or selling the invention throughout the United States of America for the term of seventeen years from the date of this patent, subject to the payment of maintenance fees as provided by law.

Bruce Lehman

Commissioner of Patents and Trademarks

Sandra L. Morton

Attest

PTO-1584

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/8[illegible].511	02/19/92	HUNTER	[illegible]

EXAMINER

15N1/0527

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

ART UNIT	PAPER NUMBER
1504	

DATE MAILED 05/27/94

A. ☐ The petition filed __________ under 37 CFR 1.312(b) is granted.
The paper has been forwarded to the examiner for consideration on the merits.

B. ☒ The amendment filed 2/16/94 under 37 CFR 1.312 has been considered, and has been:

1. ☐ entered
2. ☒ entered as directed to matters of form not affecting the scope of the invention (0.3311).
3. ☐ disapproved. A report appears below.
4. ☐ entered in part. A report appears below.

Report:

SUPERVISORY [illegible] EXAMINER
GROUP 150

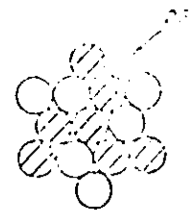
PLEASE FURNISH YOUR ZIP CODE IN ALL CORRESPONDENCE

FORM PTOL-271 (REV. 7/89)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000274

[redacted]

– 5



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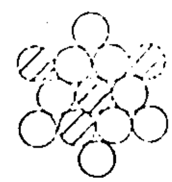

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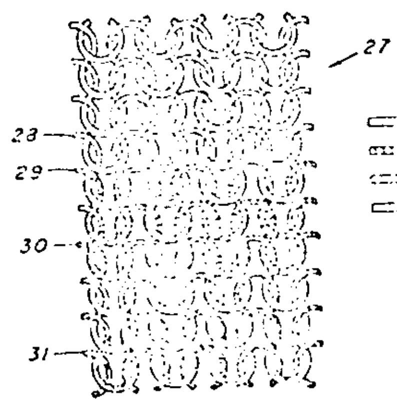


100% NON-ABSORBABLE
75% NON-ABSORBABLE – 25% PGA
50% NON-ABSORBABLE – 50% PGA
25% NON-ABSORBABLE – 75% PGA

– 5

INVENTORS.
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY
Samuel Branch Walker
ATTORNEY

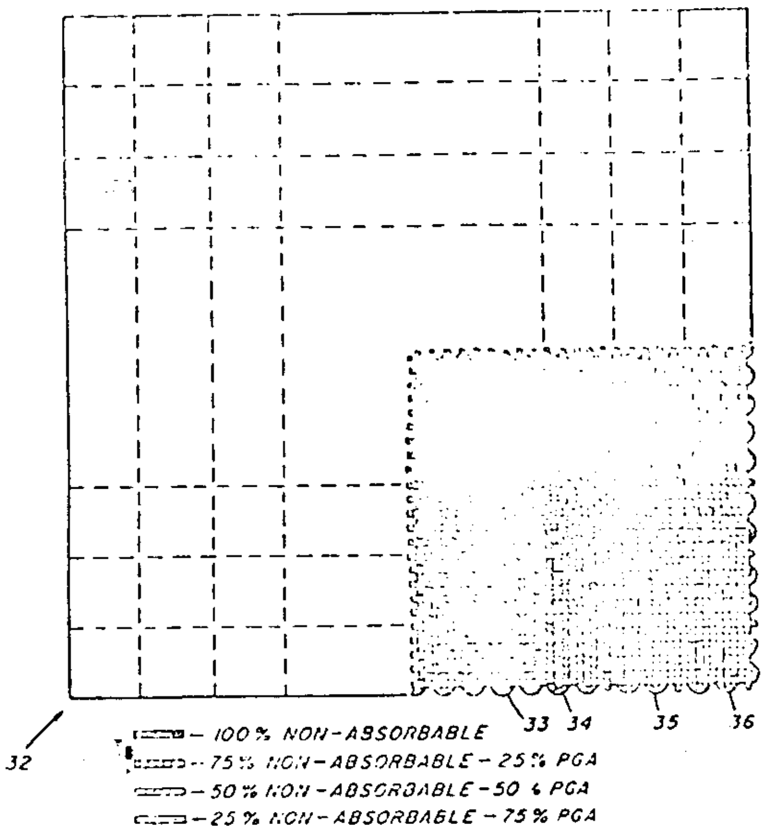


FIG - 8

INVENTORS
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY

Samuel Branch Walker

ATTORNEY

FIG-14

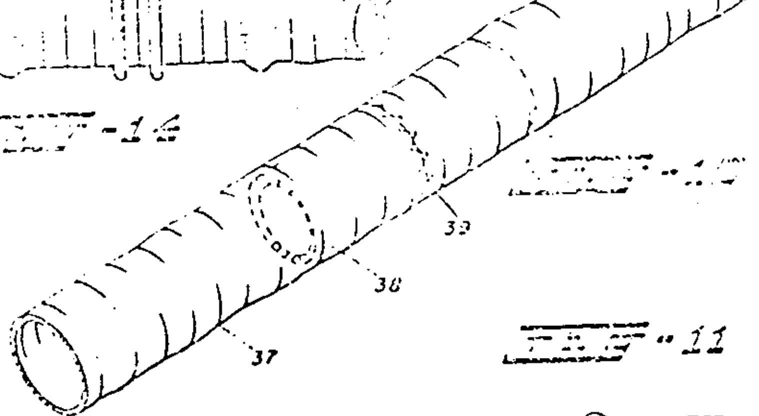
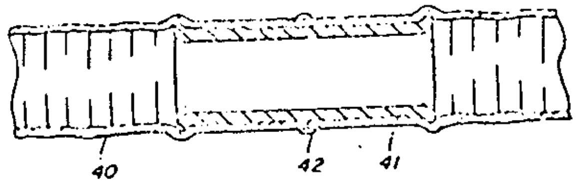


FIG-11



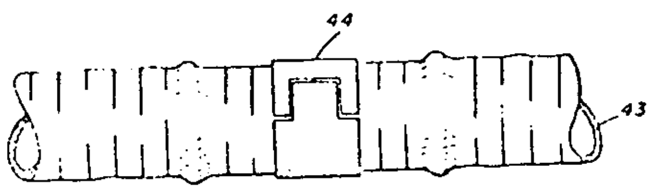


FIG-13

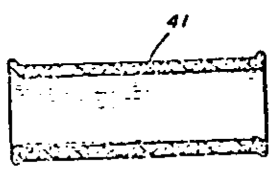


FIG-12

INVENTORS
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY
Samuel Branch Walton
ATTORNEY

FIG - 15

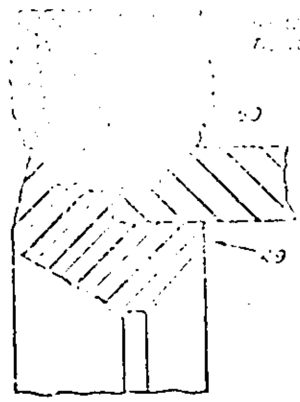


FIG - 16

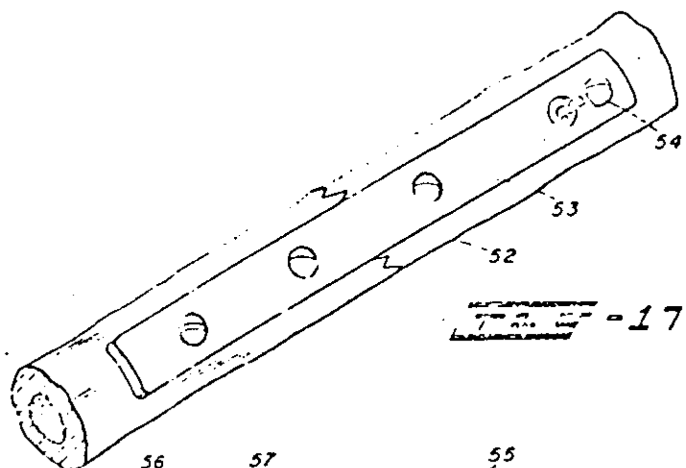


FIG - 17

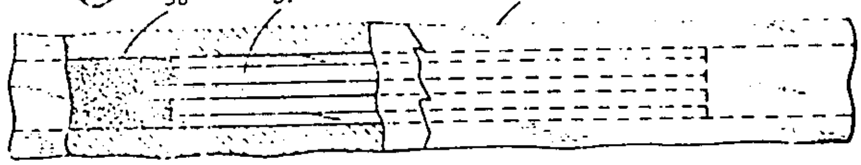


FIG - 18

INVENTORS.
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY

Samuel Branch Walker

ATTORNEY

U.S. Cl. 128—334

ABSTRACT OF THE DISCLOSURE

Polyhydroxyacetic ester, also called polyglycolic acid (PGA), has [illegible] ... crete areas with non-absorbable [illegible]. In [illegible], on implantation, in living mammalian tissue, the polyglycolic acid is absorbed, and replaced by living tissue. Fabric structures of an intermixture of PGA and non-absorbable material are particularly useful in tissue repair or replacement so that living tissue mechanically unites about the non-absorbable fiber structure, locking it into place.

CROSS REFERENCES

This application is a continuation-in-part of application Ser. No. 320,543, filed Oct. 31, 1963 now U.S. Patent 3,297,033, Jan. 10, 1967, "Surgical Sutures."

Field of invention

This invention relates to absorbable surgical elements of polyhydroxyacetic ester hereafter called polyglycolic acid (PGA).

Prior art

The use of submucosal tissue and ribbons therefrom internally is described in such patents as United States Patent 2,167,251, Rogers, "Surgical Tape of Sumucosa Tissue," July 25, 1939, United States Patent 2,143,910, Didusch, "Ribbon Gut and Method of Using the Same," Jan. 17, 1939, and United States Patent 2,127,903, Bowen, "Tube for Surgical Purposes and Methods of Preparing and Using the Same," Aug. 23, 1938.

U.S.P. 2,836,181, J. S. Tapp, "Flexible Nylon Tube and Method for Preparing Same" shows a braided heat crimped formic acid treated nylon tube spliced into a blood vessel, with the crimp permitting a desired degree of flexibility.

U.S.P. 3,099,0[illegible], M. L. Edwards, "Heart Valve" shows a plastic cardiac valve, in which a fabric is emplaced in a ring around the valve, and sutured to the heart tissue, to permit the heart tissue to grow to such fabric, and hold the valve in position in the heart.

U.S.P. 3,054,406, F. C. Usher, "Surgical Mesh," Sept. 18, 1962, shows the use of a polyethylene woven mesh fabric implanted in the human abdominal wall for reinforcing and healing defects.

U.S.P. 3,108,357, W. J. Liebig, "Compound Absorbable Prosthetic Implants, Fabrics and Yarns Therefor" shows flexible fabrics of mixed absorbable and non-absorbable textile fibers for implantation, and reinforcement of tissue.

U.S.P. 3,124,136, F. C. Usher, "Method of Repairing Body Tissue," Mar. 10, 1964, shows the use of knitted linear polyethylene mesh attached to [illegible] defect. The polyethylene is [illegible] and permanently reinforces the tissue at the [illegible] of the defect. Additional details appear in Usher, [illegible] on Marlex Mesh in the Repair of [illegible] The American Surgeon 24, [illegible]

[illegible] surgical prostheses.

SUMMARY

[illegible] terms are [illegible]:

A "filament" is a [illegible] of a non-absorbable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a long, continuous thread.

Non-absorbable surgically acceptable filaments include filaments of polyalkylenes, such as polyethylene, preferably linear polyethylene with a density of about 0.94 or higher, or polypropylene, preferably [illegible] polypropylene; or a polyamide, such as nylon; or a polyester, such as Dacron; or a polyacrylonitrile, such as Orlon or Creslan; or a halogenated polyalkylene, such as polytetrafluoroethylene, such as Teflon, or other halogenated polyalkylene, such as Kel-F or FEP; or cotton, or silk, or linen; or a metal such as stainless steel, tantalum, silver, gold, or platinum. The above are illustrative. Any non-absorbable material which is essentially inert in living mammalian tissue, particularly human tissue, is usable as a non-absorbable filament. Those materials having a comparatively high tensile strength and flexibility are preferred.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

A "bicomponent filament" is a filament composed of two separate materials. As used herein, the term is limited to a filament having one non-absorbable component and one absorbable component. The components may be adjacent. The most easily formed and preferred bicomponent filament is a sheathed filament with an internal non-absorbable material coated, or sheathed, approximately concentrically, with an absorbable component.

A "bicomponent thread" includes a thread of bicomponent filaments or a blend of different separate monofilament components twisted together, or both.

A "bicomponent strand" is a strand of one or more bicomponent filaments, or two different filament materials, or both, at least one component of which is absorbable.

A "bicomponent fabric" is a woven, knitted, felted, adhesively united, or otherwise formed [illegible] at least two [illegible] component materials or [illegible] components, at least one component [illegible] absorbable.

A "coated fabric" is a fabric [illegible] with a [illegible] continuous [illegible] example by [illegible] system of [illegible] may [illegible]

[illegible] factors may be considered [illegible]. PGA is [illegible] useful in [illegible] PGA is completely dissolved in [illegible] leaves minimal or no residual scar tissue from the PGA.

A "gradual transition section" is a portion of bicomponent fabric, or [illegible] component strand, which by selection of strands for the fabric, or components for the strand or strands, has a changing composition, over a short distance, of 1 mm. to 15 mm. or more, so that a fabric or strand changes in composition from nonabsorbable material, or substantially non-absorbable material, to predominantly or completely absorbable material, whereby living tissue can replace the absorbable component and a gradual transition accomplished between the nonabsorbable reinforcing prosthesis and the adjacent living tissue. With an arterial implant, for instance, a post cause of trouble has been the line of juncture between the implant and the natural artery wall. With a gradual transition, no sharp line of demarkation exists, and, hence, failures between the prosthesis and tissue are minimized. With implants of the types shown by Usher, supra, the edges of the reinforcing element could cause difficulties. With a gradual transition, a line of potential risk is eliminated.

For different purposes and in different types of tissue the rate of absorption may vary but in general an absorbable prosthesis should have as high a portion of its original strength as possible for at least three days, and sometimes as much as fifteen days or more, and preferably should be completely absorbed by muscular tissue within from forty-five to ninety days or more depending on the mass of the cross-section. The rate of absorption in other tissues may vary even more.

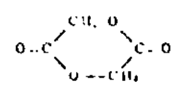
In common with many biological systems, the requirements are not absolute and the rate of absorption as well as the short-term strength requirement varies from patient to patient and at different locations within the body, as well as with the thickness of the section of PGA.

The PGA may be formed as tubes or sheets for surgical repair and may also be spun as thin filaments and woven or felted to form absorbable sponges or absorbable gauze, or used in conjunction with other structures as prosthetic devices, within the body of a human or animal where it is desirable that the structure have short-term strength, but be absorbable. The useful embodiments include tubes, including branched tubes or T's, for artery, vein or intestinal repair, nerve splicing, tendon splicing, sheets for tying up and supporting damaged [illegible] and other intestinal organs, protecting damaged surface areas such as abrasions, particularly [illegible] areas where the skin and underlying tissues are damaged or surgically removed.

The synthetic character and hence predictable formability and [illegible] obtainable from a controlled process [illegible]

[illegible] 245° C. [illegible] 27,000 poises. [illegible] controllable source, with a controlled [illegible] weight and controlled small percentage of [illegible], the absorbability, stiffness, and other characteristics can be modified.

Among several methods by which PGA can be prepared, one preferred route involves the polymerization of glycolide,



the cyclic dimeric condensation product formed by dehydrating hydroxyacetic acid. During polymerization of glycolide, the ring is broken and straight-chain polymerization occurs.

Small quantities of other materials may be present in the chain, as for example, d,l-lactic acid, its optically active forms, homologs, and analogs. In general, plasticizers tend to interfere with crystallinity, orientation, etc. and weaken fibers, but are useful for sponges and films. Other substances may be present, such as dyes, antibiotics, antiseptics, anesthetics, and antioxidants. The surfaces of the fabric can be coated with a silicone, beeswax, and the like to modify the handling or absorption rate.

The polymerization of glycolide occurs by heating with or without a catalyst, or may be induced by radiation such as X-rays, gamma rays, electron beams, etc. Polymers may also be obtained by condensing glycolic acid or chloroacetic acid with or without a catalyst under a variety of conditions. Good moldable objects or fibers are most readily obtained when the melt viscosity at 245° C. is about 400 to about 27,000 poises.

Polyhydroxyacetic esters have been described in United States Patent 2,668,162, Lowe, "Preparation of High Molecular Weight Polyhydroxyacetic Ester," and United States Patent 2,676,945, Higgins, "Condensation Polymers of Hydroxyacetic Acid."

The processes described in the above two patents can be used for producing PGA from which prostheses may be made. Additives such as triphenylphosphite or Santo-Nox, a disulfide aromatic phenol, can be added as color stabilizers.

DRAWINGS

FIGURE 1 shows a cross-section of a bicomponent filament of [illegible] coated [illegible]

FIGURE 2 [illegible] cross-section of [illegible] filament [illegible]

FIGURE 3 [illegible]

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000280

[illegible]

FIGURE 11 is a cross-section of [illegible] an internal sleeve with expanded ends.

FIGURE 12 shows a prosthetic sleeve formed of [illegible] tary coupling of solid polyglycolic acid with [illegible] pointing ends to aid in holding a blood vessel [illegible] sleeve.

FIGURE 13 shows the sleeve of FIGURE 12 in use in which an external spring clip of solid polyglycolic acid holds the ends of the blood vessel together.

FIGURE 14 shows the sleeve of FIGURE 12 [illegible] two expandable annular clips are used to hold the ends of the blood vessel approximated.

FIGURE 15 is a portion of a woven tube of [illegible] individual strands which are at least in part [illegible].

FIGURE 16 shows a portion of a heart valve [illegible] in heart tissue using a fabric in part composed of polyglycolic acid to aid in holding the valve in place.

FIGURE 17 shows a broken bone, the ends of which are held together by a solid bar of polyglycolic acid held to the bone by polyglycolic acid screws.

FIGURE 18 shows a broken bone, the ends of which are held in position by an internal fluted pin of polyglycolic acid.

PGA for the construction of the prostheses shown in the drawings can be produced as set forth in the following examples, in which parts are by weight, unless otherwise clearly indicated:

EXAMPLE 1

100 parts of recrystallized glycolide (melting point 85.0 to 85.5° C.) are intimately mixed with 0.02 part of methoxyacetic acid, 0.03 part of phenoldisulfide (Santo-Nox), and 0.03 part antimony trifluoride. Separate glass tubes are each charged with approximately 20 grams of the mixture, deoxygenated by repeated evacuation and argon purging, then sealed under vacuum and heated to 185 to 190° C. for 4½ hours. On cooling a white opaque tough PGA is produced in a 97.5% yield with a melt viscosity at 245° C. of 5,000 poises. The polymer is re-heated and spun into filaments at a temperature of about 230° C. at a speed of about 150 feet per minute. The filaments produced are cooled, then drawn at about 55° C. When drawn to five times the original length a strong tough filament is produced. The dry filaments are in condition for use.

EXAMPLE 2

The polymer of the preceding example is formed into a plurality of smaller filaments, [illegible] twisted into a polyfilamentary strand, which [illegible] and used following the techniques of [illegible].

Because it is a synthetic polymer [illegible] ing are more versatile than in starting [illegible] curring materials.

[illegible] of $SnCl_2 \cdot 2H_2O$.

[illegible] a bore of about [illegible] is charged with 3 parts of the [illegible] composition, 0.01 part of [illegible] $2H_2O$ [illegible] based on the weight of the substantially pure [illegible] composition, 0.0165 part of lauryl alcohol [illegible] based on the moles of the [illegible] composition, and a magnetic steel ball [illegible] in diameter. The tube is evacuated and purged with argon. The tube is evacuated again to a vacuum of less than 1 mm. of Hg and the top is sealed. The reaction tube is placed in a vertical position in a closed glass chamber throughout which dimethyl phthalate is refluxed at 222° C. The boiling point of the dimethyl phthalate is controlled by decreasing the pressure of the system. At periodic intervals after melting, the viscosity of the reaction mixture is measured by raising the steel ball by means of a magnet and measuring the rate of the fall of the ball in sec./in. Ninety minutes after the melt is first achieved, the ball drop time is 550 sec./in. or about 7200 poises, and after 120 minutes, the ball drop time is 580 sec./in. or about 7500 poises.

The PGA thus produced is spun into .002 inch diameter fibers and used to form bicomponent strands.

Additional PGA, similarly produced is used to coat Dacron filaments, in varying weight ratios to form bi-component strands which are braided into tubular arterial implants to splice into sections of arteries.

Additional PGA, similarly produced is used to form sheets. These sheets are wrapped around nerves, traumatically severed, to protect such nerves from invasive scar tissue growth, while the nerve is regenerating.

Also the PGA so produced is fabricated into the prosthetic devices shown in the drawings.

As is shown in the drawings, a bi-component filament 23 was formed by dipping a non-absorbable filament 21 of Dacron into a PGA melt forming a PGA coating 22 on the surface of the non-absorbable Dacron 21.

As shown in FIGURE 1 the dip was such that approximately 25% of the cross section was of Dacron and 75% of PGA.

In FIGURE 2 the structure is the same except that the relative proportions are changed to approximately 50% of each material.

In FIGURE 3 the structure is the same except that the proportions are [illegible] such that approximately 75% of the [illegible] is of Dacron and about 25% on the [illegible].

[illegible] filament is shown.

[illegible] of a bicomponent [illegible] consists of 3 non-

[illegible]

It is to be [illegible] [illegible] [illegible] [illegible] [illegible]

FIGURE 8 shows a [illegible] warp and [illegible] weave [illegible] 33, 33 [illegible] with a 100% nonabsorbable [illegible] tion, and changing by 25% [illegible] 34, 35 until the [illegible] set of [illegible] is 25% nonabsorbable and 75% PGA.

Such a construction permits the [illegible] polyethylene or [illegible] polypropylene [illegible] the construction of a repair patch, such as shown [illegible] in which gradation from the [illegible] sorbable material to absorbable [illegible] the spacing between the threads in the [illegible] can be chosen for a particular application. [illegible] of the prosthetic device is to be used for the repair of [illegible] a comparatively widely spaced weave is desired. If used for an area in which liquid retention is critical, such as an artery or vein, the weave is much closer.

In FIGURE 9 is shown a knitted fabric 27, in which the respective strands are 100% nonabsorbable 28, followed by two rows of 75% nonabsorbable 25% PGA 29 followed by two rows of 50% nonabsorbable 50% PGA 30, followed by two rows of 25% nonabsorbable 75% PGA 31.

In such a graded construction, the rate of change with distance or the number of rows of a particular composition are adjusted to fit the desired use. For smaller patches the width of each proportion of components is smaller than for large patches.

In FIGURE 10 is shown an artery 37 which is joined together over a tapered end PGA tube 38 which forms a stent about which the ends of the artery wall are joined by a suture splice 39. The tapered end is easier to insert in the artery.

In FIGURE 11 the artery walls 40 are joined together over a flared end PGA tube 41 and the ends are joined by a suture splice 42.

FIGURE 12 shows the flared end PGA tube 41.

In FIGURE 13 is shown a blood vessel 43, the ends of which are each separately placed over the end of a flared PGA tube and which blood vessel is held in place with the ends adjacent to permit healing by a PGA spring clip 44. PGA, such as produced in the above Example 3, shows an Izod impact strength of 0.14 ft. lbs. per inch width or greater. It may be heated and formed into a desired shape which shape is retained on cooling, and by shaping as a flat spring clip, can be used to hold together the walls of a blood vessel 43 until natural [illegible] takes place.

In FIGURE 14 is shown a [illegible] splice of a blood vessel 45 but in which the ends are held together by an annular clip 46 of [illegible] PGA. [illegible] clips are well known for the [illegible] arteries in animals [illegible] or other flexible tubing to connect [illegible] of diameter and shape, as is well [illegible] compression at [illegible] may be [illegible] to be [illegible] [illegible] This is important [illegible] blood vessels [illegible]

[illegible]

FIGURE 17 [illegible] 52 [illegible] PGA [illegible] 54.

FIGURE 18 shows a [illegible] of [illegible] 55 [illegible] a PGA [illegible] pin 57 [illegible] to the bone marrow 56. The [illegible] of such size and shape as to fill the hollow in the bone and give [illegible] strength and prevent motion at the break.

Absorbable splices or bone pins hold the bone in place until it has an opportunity to knit and then [illegible] dissolve. In the past metallic reinforcing elements have frequently been used. Such metallic elements add weight to the body, and perhaps cause inflammation by their physical presence [illegible] must be removed at a separate subsequent operation. Additionally, if a bone pin is used internally of a bone, the volume of bone marrow is invariably reduced. When the PGA bone pin dissolves, no scar tissue remains and bone marrow is regenerated through the bone permitting the bone marrow to accomplish its organic functions.

The drawings above are illustrative only of embodiment of the present invention in which various prosthetic devices are incorporated into the human body to aid impaired functions of natural elements. From the above drawings and descriptions, it will be obvious to those skilled in the art that many other modifications may be adapted for particular injuries or ills to which the flesh is heir.

The finding that polyglycolic acid, abbreviated PGA, is absorbable in living tissue, and has marked mechanical strength, as a fiber or solid, including sheet, and hence can be used as an element in, or as, a surgical prosthesis, is most unexpected and unpredictable.

Catgut, or regenerated collagen has in the past been used for tissue emplacement, but with collagen, as the collagen is absorbed, a fibrotic tract replaces the collagen, so that in effect scar tissue remains at the site of the emplanted collagen for many years, in many instances for life. Some patients are allergic to collagen. PGA is not a protein, has no amino acids, and has given no evidence of allergic reactions in thousands of implants. With the present PGA prostheses, the PGA is completely absorbed, and a minimal or no trace of the inserted matter remains after a comparatively short period. This complete absorption, without residual fibrotic tissue, is unique, and an important contribution to surgery.

As it is obvious that examination of such prosthetic devices in humans must wait until autopsy, after [illegible] causes, experimental results were conducted on [illegible] animals which permit sacrifice and [illegible] selected periods. These are shown in the following examples:

EXAMPLE 4

Absorbable intermedullary rod

[illegible] incisions were made on the [illegible] of the hind legs of anesthetized rabbits to expose the [illegible]

[illegible] ... at the end of [illegible], 12, [illegible] and 24 [illegible] the [illegible] which [illegible] examined. These [illegible] treated femurs which had [illegible] Type 316 stainless steel [illegible] of [illegible] to those made of PGA.

With both the experimental and control animals the course of healing was uneventful. The [illegible] were essentially healed by the [illegible] week. After [illegible] the femurs were [illegible] longitudinally and the effect of time on the implants were observed. As expected in the [illegible] short times [illegible] the stainless steel pin was [illegible] but since the internal space was largely occluded, where the metallic pin was present, there was no marrow tissue.

Where the medullary rod of polyglycolic acid had been used, at six weeks the overall structure of the rod was essentially unchanged but there were fissures developing on the surface and the cut ends which had been sharply defined were somewhat rounded. The rod was somewhat softened on the surface. There was a progressive increase in the amount of erosion of the PGA rod [illegible] but this erosion was never associated with inflammation or other adverse reactions. By the 24th week the rod of polyglycolic acid was essentially digested and the bone now showed normal tissue architecture.

EXAMPLE 5

Absorbable bone plate affixed with absorbable pins

Femurs of the hind legs of rabbits were [illegible] as described in Example 4. The cut ends were reapproximated and immobilized by use of an internal [illegible] made from a sheet of polyglycolic acid approximately [illegible] inch thick 1/4" wide and 1 inch long, shaped to conform generally to the bone by softening the plastic with heat and premolding it about a metal rod of suitable diameter. The premolded plate was centrally located over the cut bone and while held in position, small holes were drilled through the plate and completely through the bone with a [illegible] inch drill, two holes on each side of the bone break. Small PGA nails about [illegible] inch long and slightly over [illegible] inch in diameter made by flattening rod of this diameter by pressing against a heated surface were driven through the holes in the PGA plate and completely through the bone to hold the plate in place. The [illegible] was reapproximated, the broken legs splinted and the animals were returned to their cages. X-rays were taken weekly and animals were sacrificed at 3, 6, 12, 18 and 24 week intervals. The legs which [illegible] were carefully [illegible] to determine the fate of [illegible] and [illegible] to [illegible] the course [illegible]. At 3 weeks the bone [illegible] PGA [illegible] was [illegible] break [illegible] bone was healed [illegible] PGA [illegible] [illegible]

[illegible] In this example where the arterial prostheses were to be used in rabbits, the tubes were only [illegible] in diameter.

The abdominal aorta was exposed by incision through the ventral wall; two clamps separated by about [illegible] inches were placed on the abdominal aorta just distal to the renal artery. The approximately 1 inch of the abdominal aorta between the clamps was resected and a comparable length of prosthetic tubing made as described above was sewn in place. The clamps were removed, and the animal was observed closely until blood seepage had stopped. The abdomen was then closed and the animal returned to its cage. Sacrifices were made at the end of 1, 3, 6, 12, and 18 weeks and the prosthetic implant and the neighboring tissue was examined. After the first week there was little change in the prosthesis. The pores of the fiber were closed with fibrin and some new cell growth was noticeable at the cut ends of the blood vessel. By three weeks the fibrin clots had been partially replaced by new cells which represented the partial development of a pseudo intimal lining extending from the ends of the original vessel. The polyglycolic acid filaments were still intact but were showing [illegible] of surface erosion on microscopic examination. By 6 weeks the pseudo intimal lining was complete. Blood vessels were beginning to develop in this tissue layer. Growth of cells was occurring through the pores of the prosthesis which were now substantially enlarged by the obvious diminution in size of the PGA filaments which were no longer continuous. Shredding of the PGA filaments was evident but the complete development of the pseudo intima prevented the shreds from entering the blood stream where they could represent foci for clot formation. By the twelfth week the PGA was essentially replaced by tissue elements which formed a well vascularized multicelluar layer completely capturing the polyester filaments of the prosthesis. The picture at 18 weeks was similar to that at 12 weeks with more vascularization and greater organization of the cells of the inner lining and outer surface of the prosthesis. There was a conspicuous absence of any inflammatory response of abnormal tissue reaction. The absorption of the polyglycolic acid gave sufficient space in the fiber network to permit adequate cell growth and proper vascularization so that necrosis of tissue did not develop.

So far as inspection permits, similar results appear to be obtained in humans. Of course with humans, and larger animals proportionately sized prostheses must be used.

We claim:

1. A surgical prosthesis comprising non-absorbable filaments shaped as a [illegible] reinforcing element, and [illegible] non-absorbable filaments, in at least a part of the element, a structure consisting essentially of polyglycolic acid, whereby on implantation in living [illegible] the polyglycolic acid structure is

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000283

[illegible] from [illegible]

4. [illegible] claim 2 in which [illegible]

[illegible] a section of non-[illegible] to a section in which at least a pre-[illegible]

[illegible] Cited

UNITED STATES PATENTS

[illegible]	[illegible]	[illegible]	128—331
[illegible]	[illegible]	[illegible]	128—331
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
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HERMES DECLARATION
EXHIBIT 15 – PART 8 OF 8

XR 3,636,956

[redacted]

[15] 3,636,956

[45] Jan. 25, 1972

Schneider

[54] POLYLACTIDE SUTURES

[72] Inventor Allan K. Schneider, Wilmington, Del
[73] Assignee Ethicon, Inc., Somerville, N.J.
[22] Filed May 13, 1970
[21] Appl. No.: 36,797

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 700,036, Jan. 24, 1968, abandoned, which is a continuation-in-part of Ser. No. 449,630, Apr. 20, 1965, abandoned, which is a continuation-in-part of Ser. No. 308,685, Sept. 13, 1963, abandoned, which is a continuation-in-part of Ser. No. 231,860, Oct. 19, 1962, abandoned

[52] U.S. Cl. 128/335.5, 260/78.3
[51] Int. Cl. A61l 17/00
[58] Field of Search 128/334, 335.5; 260/78.3

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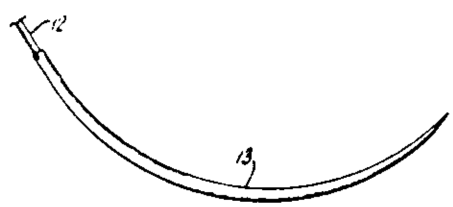
Primary Examiner—Dalton L. Truluck
Attorney—Robert W. Kell and Robert L. Minier

[57] ABSTRACT

Absorbable surgical sutures that are dimensionally stable within the body may be prepared by the extrusion of polylactide polymer, including copolymers of L(−) lactide with up to 35 mole percent of glycolide. Said polymers are characterized by an inherent viscosity of at least 1.0, and the extruded filaments are oriented by drawing at a temperature of about 50° to about 140° at a draw ratio of up to 11x, and annealed. Sutures so prepared have a tensile strength of from 25,000 p.s.i. to 100,000 p.s.i.

79 Claims, 5 Drawing Figures



PATENTED JAN 25 1972 3,636,956

Fig.1.

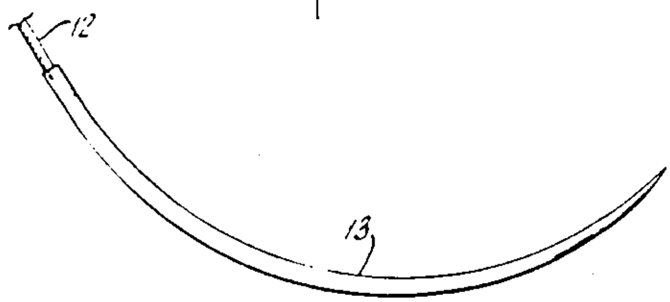


Fig.2.

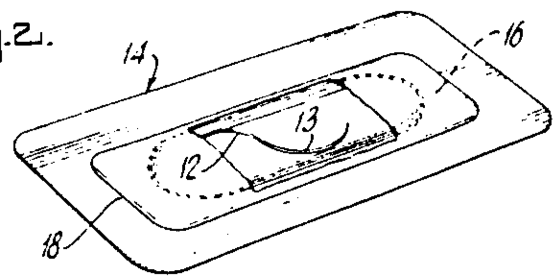


Fig.3.

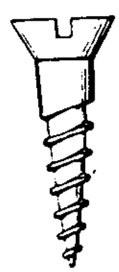


Fig.4.

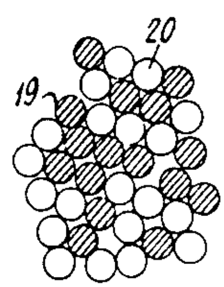
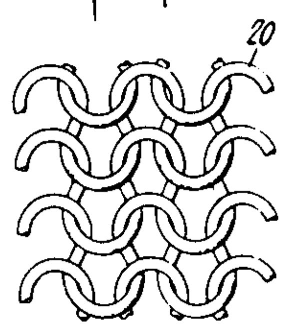


Fig.5.



INVENTOR
ALLAN K. SCHNEIDER
BY Robert W. Kell
ATTORNEY

POLYLACTIDE SUTURES

This application is a continuation-in-part of my copending U.S. application Ser. No. 700,036, filed Jan. 24, 1968, now abandoned, which in turn was a continuation-in-part of my then copending U.S. application Ser. No. 449,630, filed Apr. 20, 1965, now abandoned, which in turn was a continuation-in-part of my then copending U.S. application Ser. No. 308,688, filed Sept. 13, 1963, now abandoned, which in turn was a continuation-in-part of my then copending U.S. application Ser. No. 231,860, filed Oct. 19, 1962, also now abandoned.

This invention relates to new articles of manufacture and to their use. More particularly, the invention is concerned with surgical aids prepared from synthetic polymers including copolymers of lactic acids and their use in surgical applications, e.g., sutures and ligatures and other prosthetic devices used in joining or supporting living tissues.

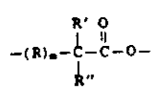
Catgut (actually from sheep or beef intestine) is the most commonly used absorbable suture now on the market. In many instances, however, it may cause adverse tissue reaction in the sutured flesh. This, together with the fact that it requires storage under moist conditions, makes it less than an ideal suture material. Nylon, stainless steel, cotton, linen, ramie, "Teflon" fluorocarbon resin, "Dacron" polyester fibers, silk, and other materials have been suggested and/or used as surgical sutures. Some of them have advantages over catgut in strength, uniformity, and storage characteristics, but they are not absorbed by living tissue.

Among the requirements of the ideal absorbable suture product are that it should handle properly, should approximate and hold tissue for proper healing with the least possible damage, should not tear tissue, should have adequate tensile strength, should be controllably uniform in properties, including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body and the condition of the patient, without causing such unfavorable tissue reactions as walling off, granuloma formation, excessive edema, etc., and finally should be capable of tying and holding surgical knots properly.

This invention fulfills the above requirements to a remarkable degree by providing highly oriented, high tenacity filaments of polymers and copolymers of lactic acid, the filaments having excellent dimensional stability in body tissue and preferably retracting less than 10 percent in an empirical test in which the filaments are immersed in water at 37° C. for a period of 24 hours.

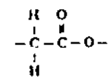
These filaments are prepared from lactic acid homopolymers and copolymers having an inherent viscosity of at least 1, preferably above 1.2, as determined at 0.1 percent concentration in benzene by weight at 25° C. prior to being oriented. Any polylactide composition containing up to about 15 percent by weight of repeating units of the formula:

(1)



wherein R is lower alkylene, preferably methylene ($-CH_2-$) or ethylene ($-CH_2CH_2-$), m is 0 or 1, R' is hydrogen or lower alkyl, R'' is hydrogen or alkyl of up to about 22 carbons when m is 0 and hydrogen or lower alkyl when m is 1, and can be the same as R' or different, can be employed to make the sutures of this invention. Preferred, because of availability of starting materials, are repeating units derived from alpha-hydroxycarboxylic acids, i.e., units of the above formula in which m is 0. Most preferred, because of the properties of the sutures made therefrom, are repeating or comonomer units derived from glycolide or DL-lactide, i.e., repeating units of formula (1) in which m is 0, R' is hydrogen or methyl, and R'' is hydrogen. In other words, the number of carbon atoms in the repeating unit is two to about 24, preferably two to about eight, and most preferably two to three. It will be understood that when m is 0, R' is methyl, and R'' is hydrogen the repeating unit in formula (1) could be derived from DL lactide. This would result in a copolymer containing both antipodal species derived from alpha-hydroxypropionic acid. When the repeating unit in formula (1) is identical with the principal unit, the polylactide composition is a homopolymer. In the specific instance when m is 0 and both R' and R'' are hydrogen, (when glycolide is the comonomer), the polylactide composition may contain about 35 mole percent of repeating units of the formula

(2)



Such copolymers of L(−) lactide and glycolide may also be employed to make the sutures of this invention.

Illustrative of the comonomers which can be employed with the lactide to form copolymers useful in preparing the filaments of this invention, there can be name glycolide, beta-propiolactone, tetramethylglycolide, beta-butyrolactone, gamma-butyrolactone, pivalolactone, and intermolecular cyclic esters of alpha-hydroxybutyric acid, alpha-hydroxyisobutyric acid, alpha-hydroxyvaleric acid, alpha-hydroxyisovaleric acid, alpha-hydroxycaproic acid, alpha-hydroxy-alpha-ethylbutyric acid, alpha-hydroxyisocaproic acid, alpha-hydroxy-beta-methylvaleric acid, alpha-hydroxyheptanoic acid, alpha-hydroxyoctanoic acid, alpha-hydroxydecanoic acid, alpha-hydroxymyristic acid, alpha-hydroxystearic acid, and alpha-hydroxylignoceric acid.

The filaments prepared from the above-described lactide polymers and copolymers are conveniently formed by melt-extruding the polylactic acid through a spinneret and then drawing the filaments in one or more stages to about four times their original length to effect orientation and to improve their tensile strength. The resultant oriented filaments are strong and retain much of their strength on being tied into surgeon's knots.

To further improve their dimensional stability and particularly tensile strength retention, one may subject them to an annealing treatment. This optional annealing treatment is effected by heating the filament, while holding it essentially taut, at 60° to 150° C., and then allowing it to cool to room temperature (25° C.) while held taut. The annealing is preferably conducted for such a time that the filament shows less than 10 percent shrinkage on subsequent immersion, for 24 hours without tension, in water at 37° C. The heating step of annealing usually requires from 0.5–5 minutes, to as long as 1 week.

A filament which meets the foregoing shrinkage test (37° C.) undergoes substantially no shrinkage when used as a suture in contact with body tissues (see example II). The conditions of this test are designed to give a quick in vitro measure of the dimensional stability of the filaments that can be projected to their usefulness as suture materials. In this connection, it should be mentioned that the conditions of draw have an influence over the shrinkage. Further, it has been found that those filaments showing little shrinkage in 24 hours at 37° C. have relatively little shrinkage when implanted in an animal body.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent separation as a result of movement or exercise, the suture should have adequate strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Filaments from lactic acid polymers in high molecular weight oriented form are exceptionally strong and most significantly retain a high proportion of their strength at the knot point, as shown in the following table.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000287

TABLE I

	Tensile strength (straight pull) p.s.i.	Percent elongation at break	Tensile strength (surgeon's knot) p.s.i.[5]	Percent loss in strength, knot vs. straight
Poly-L(−) lactide	[1] 120,000	17	85,000	29
Do	[2] 100,000	16	76,000	25
Catgut	[3] 50,000	30	29,000	42
	[4] 44,000	20	27,000	39
L(−) lactide/gamma-butyrolactone (95/5) copolymer	[6] 59,000	17	42,000	29

[1] Inherent viscosity = 2.5, 10X draw, 0.008 inch diameter.
[2] Inherent viscosity = 2.5, 10X draw, 0.008 inch diameter.
[3] Chromic gut (0.008–0.010 inch diameter).
[4] Chromic gut (0.010–0.012 inch diameter).
[5] After U.S. Pharmacopoeia
[6] Inherent viscosity (bulk polymer) = 3.0 (spun filament) = 1.6, 10X draw, 0.009 inch diameter.

As will be apparent from table I, the inherent viscosity of the spun filament, i.e., the oriented filament, may be somewhat less than that of the bulk polymer or copolymer, for during the extrusion operation some degradation of the polymer may occur depending on the extrusion conditions employed. If the sutures are sterilized by high energy radiation, there may be a further lowering of the molecular weight of the polymer, and a resulting decrease in tensile strength. However, by starting with lactide polymers and copolymers having inherent viscosities of at least 1, the sutures prepared therefrom are entirely satisfactory if one minimizes degradation during sterilization, even though there may be some loss in inherent viscosity due to extrusion and orientation.

The filaments of this invention are further characterized by their hydrolysis behavior and absorbability. On treatment with boiling water for 100 hours, they lose at least 20, and preferably at least about 50 percent, of their weight. On treatment with boiling water for a period of 50 hours, the copolymers lose at least about 8 percent of their weight, and preferably they lose at least about 35 percent of their weight.

By varying the type and amount of comonomer employed, the rate of hydrolysis (absorption) of the suture can be controlled. In contrast to the highly variable absorption rates of catgut, the absorption of polylactide polymers is relatively more independent of the place in the body where used and of the condition of the patient. Since the hydrolysis rate of a particular lactic acid polymer is constant at a fixed temperature, say, at 37° C., absorption can be speeded up, for instance, by using different copolymers. For example, poly-L-lactide was 15.3 percent absorbed in the back muscle of a rat after 270 days. Under comparable conditions, L(−)-lactide/DL-lactide (97/3) copolymer was 18.5 percent absorbed, L(−)-lactide/DL-lactide (95/5) copolymer was 29.0 percent absorbed, L(−)-lactide/glycolide (95/5) copolymer was 27.3 percent absorbed, and chromed catgut was 67 percent absorbed. The rate of absorption of a copolymer of L(−)-lactide and glycolide increase with increasing amounts of glycolide in the polymer chain.

As already indicated, high tensile strength is an exceedingly desirable characteristic for suture materials. The filaments of the present invention are characterized by having a tensile strength of at least 25,000 p.s.i., preferably above 40,000 p.s.i. Some have tensile strengths ranging up to 100,000 p.s.i. and higher. Their knot strengths, expressed in lbs. of pull, exceed the minimum limits set for absorbable sutures by the U.S. Pharmacopoeia, i.e., from 0.125 lb. for a 0.001–0.002 inch filament to 25 lbs. for a 0.036–0.040 inch filament.

In preparing the polymers and copolymers from which the filaments of this invention are made, the appropriate intermolecular cyclic ester or intramolecular cyclic ester (lactone) of the hydroxy acid is employed. These can be derived from pure D(−)- or L(+)-lactic acids, the optically inactive DL-lactic acid mixture, any desired mixtures of pure D(−)-lactic and L(+)-lactic acids, and other alpha, beta, or gamma-hydroxy acids, about which more will be said later. In general, it is preferred, for the preparation of lactic acid homopolymers and for the introduction of lactide repeating units into copolymers to use as a starting material a lactide derived from either the pure L(+)-acid or pure D(−)-acid because the polymers obtained therefrom have a higher melting point than those derived from the DL-acid mixtures, are much less water sensitive, are stronger, and have a greater degree of crystallinity. For example, the polylactides from the DL-acid melt at 130° to 140° C., whereas those from the L(+)-acid melt at 145° to 175° C. The polylactides from the L(+)-acid or D(−)-acid are less sensitive to alcohol, a commonly used disinfecting medium in surgery, than those from the DL-acid. The L(+)-form is more readily available than the D(−)-acid and hence is particularly preferred. It is to be understood that the various lactides can be made from the corresponding lactic acids by a variety of published methods including that described in Schneider U.S. Pat. No. 2,703,316.

Table II, below, summarizes data comparing the properties of polymers prepared from L(−) lactide with those prepared from DL-lactide.

TABLE II

	Polymer From	
	DL-lactide	L(−) lactide
inherent viscosity	0.7–2.0	0.7–3.5
melting point	130°–140° C	145°–175° C
optical activity	no	yes (−156°)
solubility	CHCl$_3$, benzene, acetone	CHCl$_3$, benzene, acetone
density	1.26	1.26
tensile strength at break (monofilament)	20,000–40,000 p.s.i.	70,000–100,000 p.s.i.
elongation at break (monofilament)	15–30 percent	15–30 percent
tensile strength at break (dry film)	26,000 p.s.i.*	29,000 p.s.i.*
inherent viscosity (film)	1.29*	1.27*
elongation at break (film)	48 percent*	23 percent*

In general, the tensile modulus, melting point, and specific rotation of a lactic acid polymer is maximum for the homopolymer of a single-antipodal species and decreases with increasing amounts of the other antipodal species in the polymer chain. This characteristic of lactic acid copolymers is an advantage since it permits one to choose a copolymer composition that can be extruded to form filaments which have improved flexibility, without appreciable sacrifice in strength.

*Taken from U.S. Pat. No. 2,758,987.

In preparing copolymers, the repeating units derived from comonomers discussed above are introduced by use of the appropriate cyclic esters. For repeating units derived from alpha-hydroxy acids, these are usually the intermolecular cyclic esters containing six-membered rings, e.g., glycolide. For repeating units derived from beta- or gamma-hydroxy acids, the monomeric lactones, e.g., beta-propiolactone and gamma-butyrolactone, are usually used.

The polymer filaments of the present invention may be woven, braided, or knitted either alone or in combination with nonabsorbable fibers such as nylon, polypropylene, ORLON, DACRON, or TEFLON to form tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like. The manufacture of such tubular structures wherein the wall of the tube is fabricated of absorbable and nonabsorbable threads is described in U.S. Pat. Nos. 3,304,557; 3,108,357, and 3,463,158, the teachings of which are incorporated herein by reference. Inasmuch as the polylactide filaments are thermoplastic such tubular grafts may be crimped on a mandrel at elevated temperature and upon cooling to room temperature, will retain the crimp.

Tubular structures of polylactide filaments may be prepared that are resistant to radial compression and expansion by applying a helical wrapping of polypropylene monofilament around the external surface of the tube and fusing the polypropylene to unite the helical wrapping with the polylactide filaments in the external surface of the tube as illustrated in U.S. Pat. No. 3,479,670.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws, reinforcing plates, etc., may be machined from the cast polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

The invention will appear more clearly from the following detailed description when taken in connection with the accompanying drawings which show by way of example preferred embodiments of the inventive idea. Referring now to the drawings

FIG. 1 is a perspective view of a needle-suture combination,

FIG. 2 is a perspective view of a suture-needle combination within a hermetically sealed container;

FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and,

FIG. 5 is a plan view of a knitted fabric.

In preparing the filaments of this invention, it is essential to use polymers made from highly-purified lactides. For example, for excellent results L(−) lactide should have a melting point of at least 96° C. and a specific rotation greater than −295°. The polymerization is effected by heating the lactide above its melting point, but below about 215° C. in the presence of a polyvalent metal oxide or compound thereof, under anhydrous conditions in an inert atmosphere.

Specially useful catalysts are zinc oxide, zinc carbonate, basic zinc carbonate, diethylzinc, titanium, magnesium or barium compounds, litharage, stannous octoate and the like.

The amount and type of catalyst used determine the particular temperature and time required to produce polymer useful for conversion to the filaments of this invention. Thus, the amount can be as low as 0.001 weight percent or as high as 2 weight percent. As a rule, the lower the amount of catalyst, the longer the time required to produce polymer of a given inherent viscosity and, conversely, the higher the catalyst concentration, the shorter the time. The best balance is usually obtained employing from 0.02 weight percent to 1 weight percent of catalyst.

In general, it is desirable to agitate the reaction mixture continuously during the polymerization in order to produce a homogeneous polymer at good conversions and to conduct the reaction in two steps, the first being carried out at a lower temperature than the second, or finishing step. Other methods, such as those disclosed in U.S. Pat. Nos. 2,703,316 and 2,758,987 can be used in making the polymers.

The following is a brief description of a method for preparing the polymer useful for conversion to the filaments of this invention: lactide, purified by several crystallizations from carbon tetrachloride, is placed with one or more solid comonomers in a thoroughly dried reactor equipped with a stirring bar, nitrogen inlet tube, and a drying tube filled conveniently with anhydrous magnesium sulfate or calcium chloride. Nitrogen, which has been dried by passage through anhydrous magnesium sulfate or calcium chloride, is introduced immediately above the reaction mixture and heating and stirring are started. When the temperature of the reaction mixture has reached about 100° C., the nitrogen inlet is replaced by a thermometer, and from about 0.001 to 2 weight percent of an oxide or salt, of group II metal of atomic number 12 through 56, or litharge is added. In the case of copolymerization with a liquid comonomer the liquid comonomer is preferably added after the lactide has melted. Heating is continued until polymer having an inherent viscosity of at least 1 at 0.1 percent concentration in benzene at 25° C. is obtained. This may require from a few minutes up to 25 or more hours, depending upon the catalyst used.

Polymer, produced as above, may be suitably further treated by cutting it into small pieces, dissolving in a suitable solvent, for example, benzene, toluene, or xylene, and the polymer precipitated by pouring the solution into a large volume of a nonsolvent for the polymer, desirably hexane. The precipitated polymer is removed by filtration, transferred to a blender and a nonsolvent for the polymer is added. The blender is started and after a homogeneous mixture has been obtained, the mixture is filtered. The polymer is allowed to dry on the filter and is then transferred to a vacuum oven. After drying overnight at 100° C., the polymer is removed from the oven and allowed to cool to ambient temperature.

As already indicated, the polymer material can be converted to filaments by melt-extrusion and also by spinning from solution. The diameter of the resulting filaments may be as small as 0.0001 inch or less for the individual strands making up the multifilament structures and as large as 0.045 inch for very heavy monofilament sutures. Generally, however, the filaments of this invention will not have a diameter greater than 0.020–0.025 inch. Preferred are monofilaments having diameters of about 0.001–0.020 inch and multifilament structures having individual filaments of from less than 0.00025 to 0.003 inch diameter.

It will be understood that spinning and drawing may be done singly or in multiples. To prepare multifilament braided sutures, one may take either monofilaments or groups of filaments to braid.

Spinnerets having orifice sizes of 0.005 inch or larger, say, up to 0.150 inch, are suitable for spinning monofils. In spinning from solution, the solution may be extruded either into an atmosphere heated up to or above the boiling point of the solvent or into a nonsolvent for the polymer, e.g., hexane.

After spinning, the polylactide polymer and copolymer filaments are drawn to effect orientation and to improve tensile strength. This is accomplished by drawing (permanently elongating) the filaments at a temperature between 50° C. and 140° C., preferably between 90° C. and 135° C. the preferred draw ratio being from 3:1 to 11:1. The drawing step may be conducted in one or more steps, in air or in a bath containing a liquid nonsolvent for the polymer, e.g., glycerol or water. This drawing brings about a marked increase in tensile strength and molecular orientation, as measured by the X-ray orientation angle.

Following the drawing, the filaments may be subjected to annealing. This may be carried out by running the oriented filaments from a feed roll to a takeup roll and heating the filaments between the rolls, with the takeup roll rotating at a speed ranging from the same speed of the feed roll to a speed 4 percent slower than that of the feed roll. At the first-mentioned speed ratio, essentially no shrinkage will take place, and at the second-mentioned speed ratio shrinkage will take place up to 4 percent of its length. As a consequence of this annealing, the filaments undergo essentially no shrinkage under the action of body fluids, when used as sutures.

Instead of spinning the polylactide polymers into filaments, it is possible to extrude or cast it into films, which are then drawn and annealed. The films thus treated can be cut into narrow strips for use as sutures. In the preferred embodiment the sutures are made from filaments.

As best illustrated in FIG. 1, if the polylactide filaments 12 are to be used for suturing, one end thereof may be inserted in a drilled needle 13 and securely fastened in place by swaging to form a needle and suture combination.

Polylactide filaments, unlike catgut, are adversely affected by moisture and tubing fluid. For this reason, polylactide prostheses are packaged dry in a hermetically sealed package a preferred form of which is shown in FIG. 2. Referring now to FIG. 2, there is shown a surgical package indicated generally as 14 having disposed therein a coil of polylactide suture 12 one end of which is attached to a needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000289

filled with a dry atmosphere such as nitrogen. The package is fabricated of two sheets of aluminum foil or aluminum foil plastic laminate material and heat sealed or bonded with adhesive at the skirt 18 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

It is to be understood that minor amounts of inert additives such as coloring materials and plasticizers can be incorporated in the sutures by being mixed with the copolymers by known techniques. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, and diethyl phthalate can be used to advantage, especially with poly-L lactide. Preferred plasticizers for the glycolide copolymers are dibutyl phthalate and bis 2-methoxyethyl phthalate. The amount of plasticizer may vary from 1–40 percent based on the weight of the polymer. Not only does the plasticizer render the filaments more pliable and more easy to handle, but it also helps in spinning. By the term "inert" is meant materials that are inert chemically to the polymer, and are inert to living tissue, i.e., do not cause any of the adverse effects discussed on page 2 of this specification.

The present invention may be further illustrated by the following examples:

EXAMPLE I

Filaments having a diameter of 11.5 to 12.5 mils, a modulus of 1.04×10^6, tensile strength of 47,000 lb./sq. in., a knot strength of 37,000 lb./sq. in., and an elongation at break of 21 percent, were prepared by spinning polymer from L(−) lactide, said polymer having an inherent viscosity of 2.44 (measured at 0.1 percent concentration in benzene at 25° C.), from melt at 190° C., and drawing to 6:1 ratio in glycerol at 95° C. Some of the filaments were annealed taut at 126° C. and others at 100° C. as shown in more detail in table III which follows:

TABLE III

Annealed Taut at 126° C. for 5 Min.	Shrinkage
Placed relaxed in oven at 126° C. for 5 minutes	7.4 percent
Control (i.e., not annealed)	28.2 percent
Placed relaxed in water at 100° C. for 5 minutes	13.0 percent
Control	28.2 percent
Placed relaxed in water at 77° C. for 5 minutes	1.4 percent
Control	18.0 percent
Annealed Taut at 100° C. for 5 Min.	
Placed relaxed in oven at 100° C. for 5 minutes	11.0 percent
Control	21.4 percent
Placed relaxed in water at 77° C. for 5 minutes	7.4 percent
Control	18.0 percent

Annealed filaments such as described above are particularly useful as sutures as evidenced from example II.

EXAMPLE II

A polymer of L(−) lactide, said polymer having an inherent viscosity of 1.4, was melt spun at 160° to 170° C. into a monofilament. The filament was then drawn to four times the undrawn length by passage over a metal plate heated to 90° C. The filament obtained measured 0.007 inch in diameter. To improve dimensional stability, the drawn monofilament was annealed for 3 minutes at 90°–95° C. while under tension. The drawn, annealed filament was cut to convenient length and sterilized by being placed in polyethylene bags, which were sealed and exposed to two passes under a Van de Graaff beam of 2 million electron volts (1 to 1.5 Mrads. per pass). Some of the bags contained dry monofilament, some contained monofilament in water and some contained monofilaments in ethyl alcohol.

The effect of annealing can be seen by these observations. When the annealed monofilament was heated in a dry oven at 95° C. for 3 minutes in a relaxed state, it shrank less than 4 percent. By contrast, an identical monofilament that had not been annealed shrank 25 percent. The annealed monofilament at 77° C. in water for 5 minutes shrank 14 percent.

In another experiment, the annealed monofilament was implanted in the abdominal cavity of a young adult male rat. After 16 days the implantation was removed. It had undergone less than 2 percent shrinkage.

The monofilaments thus obtained were used to connect severed muscle tissue in rats and in dogs in accordance with the following procedure:

A midline incision was made in the rat's abdominal skin, the skin was peeled back, and two small slits were then made in the abdominal muscles, one on either side of the midline. Each rat was sutured with several loops of the sterilized monofils prepared as above in one incision. Each rat had, as a control, either plain or chromic catgut suture in the other incision (size 4–0, 0.006–0.008 inch diameter). The skin was then closed and clamped. The rats were observed at regular intervals.

The sterilized monofils were tested for suturing dogs as follows: a midline incision about 3 to 4 inches long was made in the skin over the abdomen of a 6-month old dog. The skin was separated from the abdominal musculature and retracted with conventional retractors. Three incisions about 1 inch long were made through the abdominal musculature. One incision was closed with polylactic acid suture material, the other incisions were sutured with commercial catgut sutures (U.S.P. type A plain, size 4–0, and type C medium chromic, size 4–0).

Rats were sacrificed at intervals of 2, 4, 7, 14, 28, 59, 91, and 140 days. Dogs were sacrificed at 14, 23, and 50 days. In these examinations it was observed that the polylactic acid monofilaments were more slowly absorbed than plain gut. Further, it was observed that there was less general tissue reaction with the polylactic acid, as shown by gross appearance and by examination of histological sections.

EXAMPLE III

Polymer from L(−) lactide having an inherent viscosity of 3.11 at 0.1 percent concentration in benzene at 25° C., prepared by previously described methods, was converted to sutures by melt spinning, drawing, and annealing as described in example I.

EXAMPLE IV

Monofils of poly-DL-lactic acid, having an inherent viscosity of 1.42 at 0.1 percent concentration in benzene at 25° C., were tested as sutures after having been sterilized by two passages under a 2 Mev. electron beam at 1 to 1.25 Mrads. per pass. The sterilized monofils (0.006–0.008 inch diameter) were tested in suturing rats as follows:

A midline incision was made in the rat's abdominal skin, the skin was peeled back, and two small slits were then made in the abdominal muscles, one on either side of the midlines. Each rat was sutured with several loops of the sterilized monofils prepared as above in one incision and with a catgut suture as control in the other incision (unchromed, size 4–0, 0.006–0.008 inch diameter). The skin was then closed and clamped. The rats were observed at regular intervals. After approximately one month, the poly-DL-lactic acid sutures were about 50 percent hydrolyzed; tissue reaction was minimal to absent with no evidence of granuloma formation and adhesions. In the rats sutured with catgut, the catgut absorbed to about 60 percent after about 1 month, but there was pronounced tissue reaction with evidence of adhesions and granulation.

After about 60 days, both the polylactic acid and catgut sutures were absorbed, but the rats sutured with the catgut showed more scar tissue than the rats sutured with the polylactic acid.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000290

144
3CC-785

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,636,956 Dated January 25, 1972

Inventor(s) Allan K. Schneider

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 11, Table VI, under "Mole %", second occurrence, line 2 : -75- has been omitted.

Col. 11, Table VI, under "Grams", second occureence, line 2 : should read -71.4-.

Col. 12, line 8 : the degree sign should appear after "85".

Col. 12, line 59 : "Example 59" should read -Example XVIII-.

Col. 13, Table IX : the last number in the first line "Days post Implantation" should read -15-; the last number in second line should read -0.4-; the last number in last line should read -2.4-.

Col. 15, Claim 7 : "107" should read -1-.

Col. 15, Claim 15 : "114" should read -8-.

Signed and sealed this 28th day of November 1972.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents

With rabbits, the suture material was found to be completely absorbed before about 38 days, irrespective of whether it was plain catgut or polylactic acid. However, the rabbits which were stitched with the polylactic acid sutures showed no adverse tissue reactions, with no tissue walling off or covering over of the suture material, in contrast to the behavior of catgut.

A midline incision of about 3 to 4 inches long was made in the skin over the abdomen of a 6-month old dog. The skin was separated from the abdominal musculature and retracted with conventional retractors. Two incisions about 1 inch long were made through the abdominal musculature. The right side incision was closed with polylactide suture material (size 4–0). The left incision was sutured with catgut (U.S.P. type A plain, size 4–0). After 4 days the polylactide was intact with no evidence of granulation or adhesion. At the end of 14 days, the dog was again examined and at the time the incision closed with the catgut showed intense inflammatory reaction. In contrast, the incision closed with the polylactic acid suture was free of granuloma formation, and the scar was clearly visible, i.e., no inflammation was evident. In both cases, however, the suture material had been absorbed by the tissue.

EXAMPLE V

A mixture of 95 parts by weight of L(−) lactide and 5 parts by weight of DL-lactide was fused under nitrogen, and there was added 0.125 part by weight of diethylzinc as a 25 percent solution in heptane. The mixture was heated at 105° C. for 1 hour at atmospheric pressure in an atmosphere of nitrogen. The solid L(−) lactide/DL-lactide (95/5) copolymer thus obtained had an inherent viscosity of 2.63 (0.1 percent solution in benzene at 34.5° C.). The copolymer was ground to a fine powder, which was in turn pressed to a plug suitable for use in an extrusion-spinning apparatus. Filaments of the copolymer were spun at about 200° C. through a 35 mil spinneret and were drawn to 6.4 times their original length in glycerol at about 120° C. The drawn filaments had the following properties

Inherent Viscosity	1.7
Diameter	12.5 mils
Tensile Strength	58,500 p.s.i.
Elongation at break	20 percent
Modulus	1.08×10⁶ p.s.i.
Knot strength	37,000 p.s.i.
Shrinkage after 5 minutes in water at 77° C	23 percent
Weight loss after 50 hours in boiling water	38 percent
After [illegible] Days in Distilled Water at 37° C	
Inherent Viscosity	0.55
Tensile strength	19,000 p.s.i.
Weight loss	2.6 percent
After 90 Days in Distilled Water at 37° C	
Inherent Viscosity	0.36
Tensile strength	[illegible] p.s.i.
Weight loss	[illegible] percent

EXAMPLES VI-XIII

A number of other L(−) lactide copolymers were prepared and spun into filaments by the method of example V. When the comonomer was a liquid at ordinary temperature (beta-propiolactone, gamma-butyrolactone, or pivalolactone), it was added to the lactide only after the lactide had been fused. The bulk polymer properties, spinning conditions, and filament properties of these copolymers are summarized in the following table.

TABLE IV

	Examples							
	VI	VII	VIII	IX	X	XI	XII	XIII
Weight percent comonomer	7.5% DL-lactide	10% DL-lactide	15% DL-lactide	5% glycolide	10% glycolide	5% beta-propiolactone	5% gamma butyrolactone	5% pivalolactone
Inh. visc. (bulk)	2.87	2.50	2.30	2.53	2.52	1.31	2.99	2.66
Spinning temp., °C	190	205	200	210	195		170	170
Draw ratio	8.6	8.1	7.5	6.6	8.0		10	10
Drawing temp., °C	128	125	100	125	100		115	100
Inh. visc. (drawn fil.)	1.75	1.75	1.47	1.84	1.70		1.73	1.61
Diameter (mils)	11.5	11.0	12.5	10.3	8.5		9.4	8.8
Ten. strength (p.s.i.)	53,300	69,000	53,000	77,000	57,800		59,000	78,000
Elong. at break, percent	20	20.7	15.5	11	32		17	27
Modulus (p.s.i.)	1.4×10⁶	1.1×10⁶	1.1×10⁶	1.1×10⁶	0.46×10⁶			1.7×10⁶
Knot strength (p.s.i.)	37,800	37,100	30,000	43,000	27,000		42,000	48,000
Shrinkage (H_2O/77° C./5 min.), percent	13	27.5–44	72	12	73		[1] 15	[1] 15
Wt. loss (H_2O/100° C./50 hrs.), percent	44	46	65	45				
After 30 days in water at 37° C.:								
Inh. visc. (drawn fil.)		0.54		0.56			0.81	0.72
Ten. strength (p.s.i.)		23,800		26,000				
Wt. loss, percent		3.5		7.4			5.6	0.3
After 90 days in water at 37° C.:								
Inh. visc. (drawn fil.)				0.34			0.58	0.33
Ten. strength (p.s.i.)				12,000				
Wt. loss, percent				12.1			7.1	3.5

[1] About.

EXAMPLES XIV—XV

Copolymers of L-lactide with the intermolecular cyclic esters of alpha-hydroxybutyric acid and alpha-hydroxyheptanoic acid were made by essentially the method of example V.

A mixture of 44.2 parts of L-lactide and 5.8 parts of the cyclic ester of alpha-hydroxybutyric acid was fused under nitrogen, and there was added 0.08 part of 25 percent solution of diethylzinc in heptane. The mixture was heated at 105°–108° C. for 3 hours at atmospheric pressure in an atmosphere of nitrogen. The resulting copolymer of L-lactide and the intermolecular cyclic ester of alpha-hydroxybutyric acid (88.4/11.6) had an inherent viscosity of 2.15 (0.1 percent solution in benzene).

The copolymer of L-lactide and the intermolecular cyclic ester of alpha-hydroxyheptanoic acid (90/10) was prepared similarly from 45 parts of L-lactide, 5 parts of cyclic ester, and 0.08 part of 25 percent solution of diethylzinc in heptane. After the mixture was heated for 3 hours, the resulting polymer had an inherent viscosity of 2.28.

The spinning conditions and filament properties of these copolymers are summarized in table V.

The intermolecular cyclic esters of alpha-hydroxybutyric acid and alpha-hydroxyheptanoic acid were prepared essentially by the method of Bischoff and Walden, Ann. 279, 100 (1895). The sodium salts of the corresponding alpha-bromo acids were made from the acids and sodium methoxide in an ethyl ether/ethyl alcohol mixture. The cyclic esters were made by heating the sodium salts to 300°–315° C. under reduced pressure. The butyric acid derivative was purified by distillation at 78°–85° C./0.07 mm. and by crystallization from ethyl alcohol/petroleum ether, with cooling in solid carbon dioxide. The heptanoic acid derivative was purified by crystallization from pentane, with cooling in solid carbon dioxide, and from

ethyl alcohol. Both cyclic esters were characterized by elemental analyses and infrared absorption spectra.

TABLE V

Example	XIV	XV
% Comonomer (by weight)	11.6% intermolecular cyclic ester of alpha-hydroxybutyric acid	10% intermolecular cyclic ester of alpha-hydroxyheptanoic acid
Inh. viscosity (bulk)	2.15	2.28
Spinning temperature	185° C	190° C
Draw ratio	10*	8
Drawing temperature	94° C., 122° C.*	98° C
Inherent viscosity	1.42**	1.63**
Tensile strength (p.s.i.)	66,300	59,100
Elongation at break	22.3%	18.3%
Modulus (p.s.i.)	1.04×10⁶	0.95×10⁶
Shrinkage (H₂O/77° C./5 min.)	20.6%	55.0%
Weight loss (H₂O/100° C./48 hrs.	60.5%	63.6%

*The filament was drawn in two stages. In the first stage, it was drawn 7X (draw ratio of 7) at 94° C.; in the second, it was drawn at 122° C. to an extent sufficient to give an overall draw ratio of 10.

**Measured on undrawn filament. The inherent viscosities of the filaments of examples V-XIII were measured on drawn filaments.

EXAMPLE XVI

A mixture of 206 g. of powdered L-lactide/DL-lactide (90/10) copolymer and 0.6182 g. of the monosodium salt of 4-{4-(N-ethyl-p-sulfobenzylamino)diphenylmethylene}-{1-(N-ethyl-N-p-sulfoniumbenzyl)-$\Delta^{2,5}$-cyclohexadienimine}[F D & C (Food, Drug, and Cosmetic) Green No. 1] was rotated in a Fisher-Kendall mixer for 48 hours at room temperature. The resulting homogeneous mixture was pressed to a plug and spun into green monofilaments by essentially the method of example V.

EXAMPLE XVII

The weighed amounts of L(−) lactide melting at 98°–99° C. and having a specific rotation (sodium D-line,) 25° C.) of −295 to −300, and glycolide (m.p. 82.8–84.5° C.) are mixed in the quantities indicated below and added to a cylindrical tube containing stannous octoate catalyst and a magnetic stir bar. After sealing under 110 mm. of mercury pressure, the vessel is heated at 105° C. for 96 hours with magnetic stirring to yield a cylinder of solid copolymer. In each case, 0.0039 mol (0.1580 g.) of stannous octoate is used as the catalyst. The monomer initiator ratio (A/I) is 1,500.

The reacting quantities and mol percent of the comonomers investigated in this example are summarized in the following table:

TABLE VI

GLYCOLIDE Mole %	Grams	Moles	LACTIDE Mole %	Grams	Moles
20	13.3	0.116	80	66.6	0.46
25*	19.1	0.165		71.8	0.49
30	20.2	0.17	70	58.4	0.41
35	23.6	0.20	65	54.7	0.38
40	26.7	0.23	60	50.4	0.35
45	30.2	0.26	55	46.1	0.32
50	33.6	0.29	50	41.8	0.29
54	39.2	0.34	46	40.1	0.28
70	47.1	0.41	30	25.1	0.17

A similar series is run using tetraphenyl tin as a catalyst at an A/I of 2,000 with similar results.

Each copolymer (from 20 mole percent glycolide to 70 mole percent glycolide) is extruded under pressure at a temperature of 10°–220° C. through a 35-mil orifice. The extruded fiber has a diameter of 33–36 mils and is drawn to five times its original length. The extruded fibers are heated to 70°–85 C. during this drawing step.

Strong resilient fibers having excellent tensile and dry knot strength are thus obtained, the physical characteristics of these fibers being summarized in the following table.

*Used 0.1780 g. of catalyst.

TABLE VII

Glycolide, mole percent	Diameter, mils	Straight, lbs.	Diameter, mils	Dry knot, lbs.	Initiator	K/S
20	15.9	8.67	18.4	6.96	Ph	0.82
20	12.4	6.60	13.1	4.82	O	0.66
25	14.7	9.14	16.2	6.61	O	0.72
30	14.5	8.66	16.2	4.17	Ph	0.48
30	13.1	9.25	15.1	6.80	O	0.80
35	14.6	10.2	14.6	6.77	O	0.66
40	14.3	8.38	14.2	6.34	Ph	0.76
40	14.2	10.2	14.3	6.63	O	0.64
45	14.1	11.4	14.1	6.7	O	0.80
60	14.8	10.0	14.7	7.12	Ph	0.72
60	14.1	11.2	13.8	6.08	O	0.84
60	14.2	6.76	14.0	4.56	Ph	0.56

NOTE.—Ph=tetraphenyl tin, monomer/initiator ratio=2,000. O=stannous octoate, monomer/initiator ratio=1,500. K/S=dry knot straight pull ratio.

The biological behavior of the L(−)-lactide glycolide copolymers prepared in accordance with the present example is summarized in table VIII. Sections of suture material are implanted subcutaneously in rats and removed at various intervals to determine changes in tensile strength and diameter. A large increase in the diameter of a suture following implantation is an indication of shrinkage (dimensional instability).

TABLE VIII

Glycolide, mole percent		Days post implantation 0	1	6	10	15
20	Tensile strength (lbs.)	10.1	8.8	6.7	4.2	4.0
	Diameter (mils)	14.8	14.4	16.6	16.4	14.4
25	Tensile strength (lbs.)	10.1	6.8	4.0	2.3	2.0
	Diameter (mils)	14.0	14.7	18.4	18.8	14.9
30	Tensile strength (lbs.)	10.3	9.2	4.4	2.0	1.6
	Diameter (mils)	14.1	18.4	22.7	23.8	24.2
35	Tensile strength (lbs.)	10.1	6.0	1.6	.....	.....
	Diameter (mils)	12.4	28.0	34.9	.....	.....
40	Tensile strength (lbs.)	8.6	2.4	2.7	0.0	.....
	Diameter (mils)	14.0	32.8	37.4	38.1	.....
50	Tensile strength (lbs.)	8.9	2.2	1.4	0.0	.....
	Diameter (mils)	16.0	26.6	34.4	41.6	.....
60	Tensile strength (lbs.)	8.6	2.0	0.2	.....	.....
	Diameter (mils)	14.1	30.2	38.4	.....	.....

EXAMPLE VIII

Fifty-four and seven-tenths parts by weight of L(−) lactide (0.38 mols) melting at 98°–99° C. and having a specific rotation (sodium D-line, 25° C.) of −295 to −300 is mixed with 23.6 parts by weight (0.20 mols) of glycolide (m.p. 82.8°–84.5° C.) and 0.0039 mol (0.158 parts by weight) of stannous octoate in a dry PYREX glass flask containing a stir bar under dry nitrogen. The monomer initiator ratio (A/I) is 1,500. The glass flask is sealed under 110 mm. of mercury pressure and the vessel is heated at 105° C. for 96 hours with magnetic stirring to yield a solid copolymer.

The 35 mole percent glycolide-lactide copolymer so obtained is extruded under pressure at an elevated temperature through a 35 mil orifice and drawn to five times the original length. The extruded fiber is heated to 70°–85° C. during this drawing step. The biological behavior of this 35 mole percent copolymer in rats is summarized in table IX.

TABLE IX

Days post implantation	0	1	6	10	1
Tensile strength, lbs.	10.0	8.9	4.2	2.1	0.
Tensile strength, p.s.i. X 10^3	60.0	53.3	25.2	18.6	2

A 35 mole percent copolymer, prepared as described above may be extruded to form a rod that can be oriented by drawing 3x at an elevated temperature. The rod so formed will have a tensile strength greater than 25,000 p.s.i.

Although this invention has been specifically illustrated with monofilaments, the products of the present invention may also be manufactured in the form of multifilaments, that may be braided to form sutures. Filaments suitable for braiding having a diameter in the range of 0.00025–0.003 inches may be conveniently obtained by dry spinning a L(−) lactide polymer dissolved in a suitable solvent. The manufacture of a braided size 2/0 suture from multifilament obtained by dry spinning a L(−) lactide copolymer is illustrated in the following example.

EXAMPLE XIX

A round-bottomed PYREX flask having a long neck is carefully cleaned, flame dried, evacuated and purged two times with dry nitrogen. To the flask is added under a dry nitrogen atmosphere:

231.42 parts glycolide (M.P. 82.8–84.5° C.) 30.19 wt. percent
533.52 parts L(−) lactide (M.P. 98°–99° C.) 69.61 wt. percent
1.5558 parts stannous octoate. 0.20 wt. percent

The flask is evacuated to 125 mm. pressure and heated at 105° C. for 66 hours. The polymer so obtained (inherent viscosity in 0.1 percent chloroform solution = 3.2–3.4) is dissolved in dry 1, 1,2-trichloroethane (distilled from phosphorous pentoxide) to give a clear 8 percent (W/W) solution (bulk viscosity 1,600 poise).

The spin dope (8 percent solution) is heated to 90° C. and extruded through a 10-hole 0.005 inch spinneret (capillary land/diameter = 2.4) at a rate of 3 milliliters per minute into a heated column 15 feet long and 6 inches in diameter. The temperature within the heated column varied from 128° C. at the bottom to 142° C. at the top and the column is swept with hot nitrogen (131–134° C.) at a rate of 5 cubic feet per minute. The extruded filaments are taken up on a reel at a linear speed of 150 feet per minute. The inherent viscosity of the filamentary material is 3.4 indicating no degradation during the spinning process. The copolymer filament is lustrous in appearance and has the following physical characteristics:

Tensile Strength	1.0 grams/denier
Elongation	530 percent
Young's Modulus	24 grams/denier

The filament contains about 1.5 percent residual solvent.

The yarn from the takeup spool is 6-plied to 60 filaments and drawn 4.5 times at 75° C. and 25 feet per minute input speed through a tubular furnace swept with nitrogen. The drawn yarns prepared as described above have the following physical characteristics:

Tensile Strength	2.8–3.3 grams/denier
Elongation	26 percent
Young's Modulus	50 grams/denier

The individual filaments have a tensile strength of about 4.5–5.0 grams/denier; an elongation of about 38 percent and a Young's Modulus of about 45 grams per denier. The yarn is braided to form a size 2/0 braided suture, packaged in a dry atmosphere in a hermetically sealed container and sterilized by cobalt 60 gamma irradiation. The in vivo absorption characteristics of this braided suture material in rats are indicated in table X.

TABLE X

	After days post implantation				
	0	1	8	10	15
Tensile strength (X10^3 p.s.i.)	56	47	37	31	30

It will be noted from a comparison of table IX and table X that the braided structure obtained from yarn that has been dry spun from a suitable solvent (example XIX) retained in vivo tensile strength for a longer period of time than a melt extruded monofilament of similar composition (example XVIII). The improvement in in vivo tensile strength exhibited by the dry spun braided suture is such that the amount of glycolide in the lactide copolymer composition may be increased to 40 mole percent (34.8 weight percent glycolide, 65.2 weight percent L-lactide). A copolymer suture of this composition (40 mole percent glycolide 60 mole percent L-lactide) has tensile strength and absorption characteristics similar to catgut.

Multifilament yarns that contain polylactide filaments together with nonabsorbable filaments of DACRON, TEFLON, nylon, etc., are useful in the manufacture of vascular grafts. Such a multifilament yarn is illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross section 19. In FIG. 4, the fibers 20 are extruded from lactide polymer and copolymer compositions as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants. Methods of weaving and crimping vascular prostheses are described in U.S. Pat. No. 3,096,560.

Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting, and fabricating by the nonwoven felting of fibers are described in U.S. Pat. No. 3,108,357 and U.S. Pat. No. 3,463,158. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of lactide polymers and copolymers. The surgical utility of "bicomponent filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158, the teaching of which is incorporated herein by reference. Monofilaments of lactide polymers and copolymers may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney, and other internal organs.

The products of the invention are useful in surgical applications where an absorbable aid or support is required, for example, in the formation of surgical mesh, absorbable staple, artificial tendons, or cartilage material, and in other uses where a temporary aid during healing is needed. They may also be used to advantage in repairing hernias and in anchoring organs which have become loose.

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope thereof, it is to be understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

I claim:

1. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body comprising an oriented synthetic polylactide polymer containing more than about 85 percent by weight of repeating units of one antipodal species of alpha-hydroxypropionic acid and no more than about 15 percent by weight of repeating units of the formula

$$\left[-(R)_m - \underset{R''}{\overset{R'}{\overset{|}{\underset{|}{C}}}} - \overset{O}{\overset{\|}{C}} - O - \right]$$

where R is lower alkylene, m is an integer of 0 to 1, R' is selected from the class consisting of hydrogen and lower alkyl, and R'', which can be the same or different than R', is selected from the class consisting of hydrogen and alkyl of up to 22 car-

bons when m is 0 and, when m is 1, R'' is selected from the class consisting of hydrogen and lower alkyl, said polylactide before being oriented being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in benzene at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, and being further characterized by exhibiting a tensile strength of from 40,000 to about 100,000 p.s.i. and by having a diameter of 0.0005–0.045 inches.

2. The suture of claim 1, packaged in a dry atmosphere within a hermetically sealed container.

3. The suture of claim 1, packaged within an evacuated hermetically sealed container.

4. The suture of claim 1, wherein the polylactide polymer is a poly L(−) lactide containing up to 15 percent by weight of repeating units derived from DL-lactide.

5. The suture of claim 1, containing a minor amount of inert coloring agent and plasticizer.

6. The suture of claim 1, containing bis 2-methoxyethyl phthalate as a plasticizer.

7. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 107, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

8. The suture of claim 1, having a sterile needle attached to one end thereof.

9. The needle and suture combination of claim 8, packaged in a dry atmosphere within a hermetically sealed container.

10. The needle and suture combination of claim 8, packaged within an evacuated hermetically sealed container.

11. The needle and suture combination of claim 8, wherein said monofilament is a poly-L-(−) lactide containing up to 15 percent by weight of repeating units derived from DL-lactide.

12. The needle and suture combination of claim 8, wherein said monofilament is a 95/5 weight percent copolymer of L(−) lactide and DL-lactide.

13. The needle and suture combination of claim 8, wherein said monofilament contains a minor amount of inert coloring agent and plasticizer.

14. The needle and suture combination of claim 8, wherein said monofilament contains bis 2-methoxyethyl phthalate as a plasticizer.

15. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 114, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

16. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body comprising a synthetic polylactide copolymer containing at least about 65 mole percent of repeating units derived from one antipodal species of alpha-hydroxypropionic acid and not more than about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in a suitable solvent at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, and being further characterized by exhibiting a tensile strength of from 40,000 p.s.i. to about 100,000 p.s.i. and by having a diameter of 0.0005–0.045 inches.

17. The suture of claim 16, packaged in a dry atmosphere within a hermetically sealed container.

18. The suture of claim 16, packaged within an evacuated hermetically sealed container.

19. The suture of claim 16, wherein the polylactide copolymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

20. The suture of claim 16, wherein the polylactide copolymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

21. The suture of claim 16, wherein the polylactide copolymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

22. The suture of claim 16, wherein the polylactide copolymer contains about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid.

23. The suture of claim 16, wherein the polylactide copolymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

24. The suture of claim 16, wherein the polylactide copolymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

25. The suture of claim 16, containing a minor amount of inert coloring agent and plasticizer.

26. The suture of claim 16, containing bis 2-methoxyethyl phthalate as a plasticizer.

27. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 16, whereby said suture becomes imbedded in the tissue,

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

28. The suture of claim 16, having a sterile needle attached to one end thereof.

29. The needle and suture combination of claim 28, packaged in a dry atmosphere within a hermetically sealed container.

30. The needle and suture combination of claim 28, packaged within an evacuated hermetically sealed container.

31. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

32. The needle and suture combination of claim 28, wherein the polyactide polymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

33. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

34. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 20 mole percent of repeating units derived from alpha hydroxyacetic acid.

35. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

36. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

37. The needle and suture combination of claim 28, wherein said monofilament contains a minor amount of inert coloring agent and plasticizer.

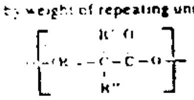
38. The needle and suture combination of claim 28, wherein said monofilament contains bis 2-methoxyethyl phthalate as a plasticizer.

39. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the needle and suture combination of claim 28, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

40. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body in the form of a braided structure, comprising filaments of a synthetic polylactide polymer containing at least about 85 percent by weight of repeating units of one antipodal species of alpha-hydroxypropionic acid and no more than about 15 percent by weight of repeating units of the formula



where R is lower alkylene, *m* is an integer of 0 to 1, R' is selected from the class consisting of hydrogen and lower alkyl, and R'', which can be the same or different from R', is selected from the class consisting of hydrogen and alkyl group of up to 22 carbons when *m* is 0 and, when *m* is 1, R'' is selected from the class consisting of hydrogen and lower alkyl, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in benzene at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, at least 50 percent of the filaments making up the braided structure being oriented and the diameter of the filaments ranging from 0.00025 to 0.003 inches; and the braided structure itself being characterized by exhibiting a tensile strength of from 40,000 p.s.i. to about 100,000 p.s.i.

41. The suture of claim 40, packaged in a dry atmosphere within a hermetically sealed container.

42. The suture of claim 40, packaged within an evacuated hermetically sealed container.

43. The suture of claim 40, wherein the polylactide copolymer filaments that make up said braided structure contain up to 15 percent by weight of repeating units derived from DL-lactide.

44. The suture of claim 40, wherein the polylactide copolymer filaments that make up said braided structure are a 95/5 weight percent copolymer of L(−) lactide and DL-lactide.

45. The suture of claim 40, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer.

46. The suture of claim 40, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer.

47. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 40, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

48. The suture of claim 40, having a sterile needle attached to one end thereof.

49. The needle and suture combination of claim 48, packaged in a dry atmosphere within a hermetically sealed container.

50. The needle and suture combination of claim 48, packaged within an evacuated hermetically sealed container.

51. The needle and suture combination of claim 48, wherein the polylactide copolymer filaments that make up said braided structure contain up to 15 percent by weight of repeating units derived from DL-lactide.

52. The needle and suture combination of claim 48, wherein the polylactide copolymer filaments that make up said braided suture are a 95.5 weight percent copolymer of L(−) lactide and DL-lactide.

53. The needle and suture combination of claim 48, wherein the filaments that make up said braided suture contain a minc. amount of inert coloring agent and plasticizer.

54. The needle and suture combination of claim 48, wherein the filaments that make up said braided suture contain bis 2-methoxyethyl phthalate as a plasticizer.

55. A method of retaining living tissue in a desired location and relationship during a healing process which comprises

sewing living tissue with the suture and needle combination of claim 47, whereby said suture becomes imbedded in the tissue,

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process

56. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body in the form of a braided structure comprising filaments of a synthetic polylactide copolymer containing at least 60 mole percent of repeating units derived from one antipodal species of alpha-hydroxypropionic acid and no more than 40 mole percent of repeating units derived from alpha-hydroxyacetic acid, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in a suitable solvent at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, at least 50 percent of the filaments making up the braided structure being oriented, and the braided structure itself being further characterized by exhibiting a tensile strength of at least 15,000 p.s.i. 10 days following implantation in an animal body

57. The suture of claim 56, packaged in a dry atmosphere within a hermetically sealed container

58. The suture of claim 56, packaged within an evacuated hermetically sealed container

59. The suture of claim 56, wherein the polylactide copolymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid

60. The suture of claim 56, wherein the polylactide copolymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

61. The suture of claim 56, wherein the polylactide copolymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

62. The suture of claim 56, wherein the polylactide copolymer contains about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid

63. The suture of claim 56, wherein the polylactide copolymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid

64. The suture of claim 56, wherein the polylactide copolymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

65. The suture of claim 56, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer.

66. The suture of claim 56, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer.

67. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 56, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

68. The suture of claim 56, having a sterile needle attached to one end thereof.

69. The needle and suture combination of claim 68, packaged in a dry atmosphere within a hermetically sealed container.

70. The needle and suture combination of claim 68, packaged within an evacuated hermetically sealed container.

71. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

72. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

73. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid

74. The suture of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid

75. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid

76. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided

structure contain about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

77. The needle and suture combination of claim 68, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer.

78. The needle and suture combination of claim 68, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer.

79. A method of retaining living tissue in a desired location and relationship during a healing process which comprises

sewing living tissue with the needle and suture combination of claim 68, whereby said suture becomes imbedded in the tissue,

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

* * * * *

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000297

ited States Patent [19] | [11] 4,141,087
iby et al. | [45] Feb. 27, 1979

ISOMORPHIC COPOLYOXALATES AND SUTURES THEREOF

Inventors: Shalaby W. Shalaby, Long Valley; Dennis D. Jamiolkowski, Paterson, both of N.J.

Assignee: Ethicon, Inc., Somerville, N.J.

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Field of Search .... 260/75 R, 860; 3/1, 3/1.4, 1.5; 128/92 B, 92 C, 334 R, 335.5

References Cited

U.S. PATENT DOCUMENTS

11,251	2/1937	Carothers	260/78 A
11,762	3/1938	Ellis	260/75 R
12,652	9/1960	Beindorff et al.	260/30.6
13,901	5/1975	Coquard et al.	128/335.5
12,993	7/1977	Coquard et al.	128/335.5

OTHER PUBLICATIONS

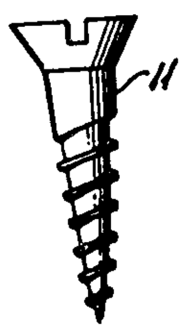
Korshak, V.V., et al., Acad. Sci. USSR Bull., Division of Chemical Sciences, pp. 889-893 (1957).
Korshak, V.V., et al., "Polyesters", Pergamon Press, N.Y., N.Y., pp. 31-63 (1965).

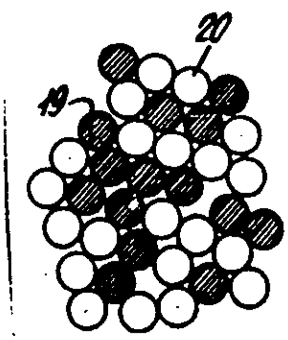
Primary Examiner—Benjamin R. Padgett
Assistant Examiner—T. S. Gron
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] ABSTRACT

Synthetic absorbable sutures are prepared from copolyoxalate polymers having isomorphic sequences. The polymers are derived from mixtures of cyclic and linear diols, each having the same carbon chain length of 6 or 8 atoms. The cyclic diol may be aliphatic or aromatic. The diols are polymerized with dialkyl oxalate, preferably in the presence of an inorganic or organometallic catalyst, to obtain a highly crystalline isomorphic copolyoxalate polymer which is melt extruded and drawn to form oriented filaments. The filaments are characterized by good initial tensile and knot strength and a high order of softness and flexibility. When implanted in living animal tissue, the fibers have good strength retention over a period of at least 21 days and eventually absorb with a minimal degree of adverse tissue reaction.

21 Claims, 5 Drawing Figures





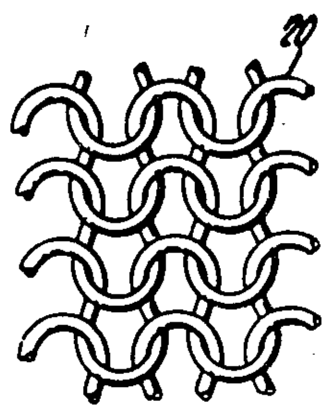


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Fig. 1.

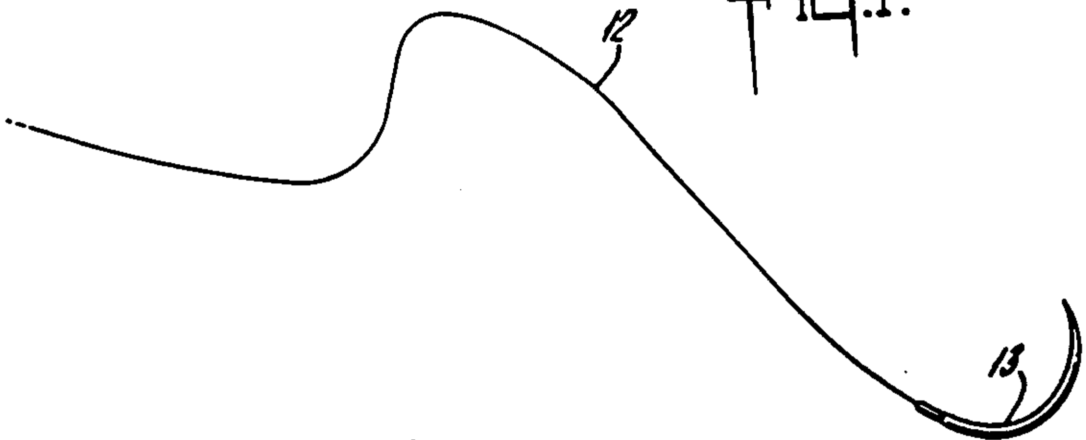


Fig. 2.

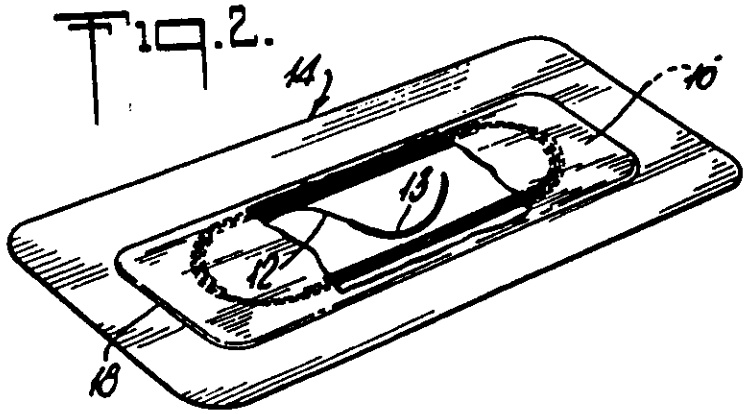


Fig. 3.

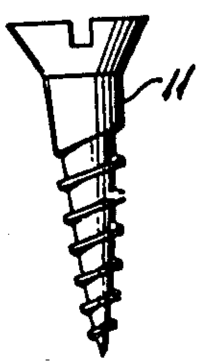


Fig. 4.

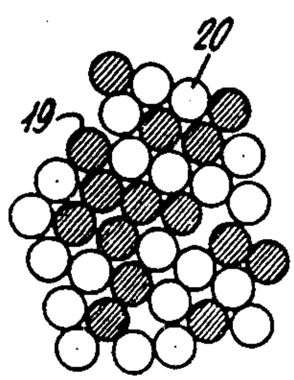
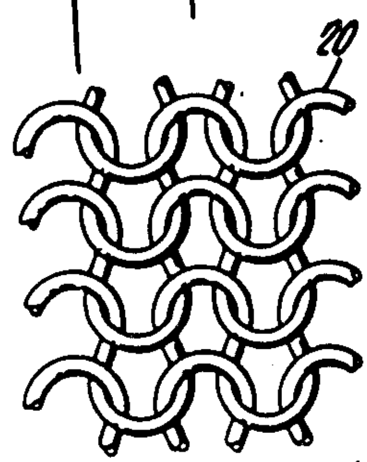


Fig. 5.



ISOMORPHIC COPOLYOXALATES AND SUTURES THEREOF

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to synthetic absorbable sutures, and more particularly, to synthetic absorbable sutures comprising extruded and oriented filaments of copolymers of polyoxalates having isomorphic sequences.

2. Description of Prior Art

Absorbable suture materials have traditionally been natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable sutures from polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable sutures are described in U.S. Pat. Nos. 3,636,956 3,297,033 and elsewhere in the literature. Polyesters of succinic acid have also been suggested for at least partially bioresorbable surgical articles as disclosed for example in U.S. Pat. No. 3,883,901.

Among the requirements of an ideal absorbable suture are that it should have good handling properties, should approximate and hold tissue for proper healing with minimal tearing and tissue damage, should have adequate straight tensile and knot strength, should be controllably uniform in properties including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body or the condition of the patient and without causing such unfavorable tissue reactions as walling off, granuloma formation or excessive edema, and finally should be capable of being properly and easily tied into surgical knots.

While multifilament sutures manufactured from polymers of lactide and glycolide fulfill the above requirements to a large degree, monofilament sutures of these materials are considerably less flexible than catgut and these synthetic sutures are accordingly generally limited to a multifilament, braided construction. Sutures of glycolide polymers are also not suitable for sterilization by radiation without suffering severe degradation of physical properties.

We have discovered that copolyoxalate copolymers having isomorphic sequences can be melt extruded into pliable, monofilament fibers which have good in vivo strength retention and are absorbed in animal tissue without significant adverse tissue reaction. The fibers have good tensile and knot strength, and can be sterilized by gamma radiation without serious loss of these properties. In addition, monofilament sutures of the polymers of the present invention have a high degree of softness and flexibility not found in many synthetic absorbable sutures of the prior art.

The preparation of polyoxalate polymers is described in the art. Carothers et al, J. Amer. Chem. Soc. 52, 3292 (1930) for example, describes the ester interchange reaction of diols such as ethylene glycol, 1,3-propanediol, or 1,4-butanediol with diethyl oxalate to yield a mixture of monomer, soluble polymer and insoluble polymer. The reaction of oxalic acid and an alkylene glycol to form polyester resins is described in U.S. Pat. No. 2,111,762, while the preparation of polyesters of fiber-forming quality from dicarboxylic acids and diols is described in U.S. Pat. Nos. 2,071,250-1 and 2,952,652. Isomorphic polymers including polyester copolymers have been discussed in the literature[1]. The particular isomorphic copolyoxalates of the present invention however, have not previously been known, nor has their preparation or use as synthetic absorbable sutures been suggested heretofore.

It is accordingly an object of the present invention to provide new and useful polymers of isomorphic copolyoxalates and articles made therefrom. A further object of this invention is to provide synthetic absorbable sutures of isomorphic copolyoxalates. It is a yet further object of this invention to provide surgical aids and prostheses fabricated of fibers or cast or machined from blocks of isomorphic copolyoxalate polymers.

SUMMARY

Highly crystalline isomorphic polyoxalate polymers are prepared by reacting mixtures of cyclic and linear diols with dialkyl oxalate, preferably in the presence of an inorganic or organometallic catalyst. The diols comprising the reaction mixture have the same carbon chain length separation between terminal OH groups of 6 or 8 carbon atoms. The cyclic diol may be trans 1,4-cyclohexane dialkanol or p-phenylene dialkanol and comprises from about 5 to 95 mol percent, and preferably from 40 to 75 mol percent of the total diol reactant.

(1) Isomorphism in Synthetic Macromolecular Systems, G. Allegra and I. W. Bassi, Adv. Polymer Sci. 6, 549 (1969)

Copolymers prepared by the transesterification reaction of the two diols and diethyl oxalate are melt extruded into highly crystalline filaments suitable for use as synthetic absorbable sutures. Drawn and oriented filaments are characterized by high tensile and knot strength, a Young's modulus in most cases of less than about 600,000 psi providing a high order of filament softness and flexibility, and good strength retention and minimal tissue reaction in vivo.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a needle-suture combination;

FIG. 2 is a perspective view of a needle-suture combination within a hermetically sealed container;

FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a surgical fabric knitted from fibers of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Polymers of the present invention are comprised of isomorphic units of cyclic and linear oxalates and have the general formula

$$\left[-O-R-O-\overset{\overset{O}{\|}}{C}-\overset{\overset{O}{\|}}{C}- \right]_n$$

wherein each R is

$$-(CH_2)_n - A - (CH_2)_n -$$

or

$-(CH_2)_{x+2}-$ II

with from about 5 to 95 mol percent, and preferably from about 40 to 75 mol percent of R groups being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

Polymers of the present invention are conveniently prepared by an ester interchange reaction between the afore-described mixture of diols and a lower ester of oxalic acid, preferably in the presence of an ester interchange catalyst. The preferred ester of oxalic acid is diethyl oxalate. The ester interchange is most preferably conducted in two stages wherein the reactants are first heated with stirring under a nitrogen atmosphere to form a prepolymer with the removal of ethanol, followed by postpolymerization under heat and reduced pressure to obtain a final polymer of the desired molecular weight and fiber forming quality. Polymers with low or moderate degrees of polymerization are postpolymerized in the liquid state or as finely-divided solid particles, depending on their melting temperature range.

The polymer is melt extruded through a spinnerette in a conventional manner to form one or more filaments which are subsequently drawn about 4X to 6X in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments have good tensile and dry knot strength and good in vivo strength retention.

It is well documented that the crystallinity and hence suitability for fiber-formation in both the AB and AA-BB type polyesters decreases significantly when the mol fraction of the major comonomer sequence decreases below about 80%. In some instances, if the comonomer sequences are isomorphic, chains composed of slightly less than 80% of the major sequences can pack into a crystalline form. However, randomly constructed copolyester chains based on almost equal amounts of the isomorphic comonomer sequences are generally found to be non-crystalline and poor fiber formers. Contrary to this general rule, the isomorphic copolyesters of the present invention display an unexpectedly high level of crystallinity of about 45% in a 50/50 copolyester. The polymers of the present invention are also unusual in that all copolymers through the entire composition range of from 5 to 95% of each isomorphic comonomer demonstrate levels of crystallinity comparable to those encountered in the parent homopolymers; namely between 30 and 50% depending on the thermal history. A similarly striking observation characteristic of these copolyesters is their display of melting endotherms, as shown by DSC, for the crystalline regions of all copolymers within the composition range of from about 5 and 95 mol % of each isomorphic comonomer. Constructed curves of the melting temperature versus composition did not reveal any positive eutectic composition in these systems. The X-ray and DSC data suggest strongly the uncommon presence of almost complete isomorphism in the copolyesters of the present invention.

Dimensional stability and tensile strength retention of the oriented filaments may be enhanced by subjecting the filaments to an annealing treatment. This optional treatment consists of heating the drawn filaments to a temperature of from about 40° to 130° C., most preferably from about 60° to 110° C. while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 60° to 110° C. for up to about 24 hours is satisfactory for the polymers of the present invention. Optimum annealing time and temperature for maximum fiber in vivo strength retention and dimensional stability is readily determined by simple experimentation for each fiber composition.

Filaments of the present invention may be used as sutures in either a monofilament or a multifilament construction. Multifilament sutures are preferably braided but may also be twisted or covered in accordance with common practice. For use as sutures, it is necessary that the fibers be sterile, and sterilization may be accomplished by exposing the fibers to Cobalt 60 gamma radiation or to ethylene oxide. Such sterilization techniques are well known and commonly practiced in suture manufacture.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent wound separation as a result of movement or exercise, a suture must meet certain minimum standards of strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Sutures prepared from oriented filaments of the present invention are characterized by a straight tensile strength of at least about 30,000 psi and a knot strength of at least about 20,000 psi, although significantly higher strengths may be obtained.

The preparation of high molecular weight oriented filaments of isomorphic polyoxalates is further illustrated by the following examples where all percentages are on a molar basis unless otherwise noted. The following analytical methods were used to obtain the data reported in the examples. Inherent viscosity (η_{inh}) was obtained on polymer solutions (1 gram/liter) in chloroform or hexafluoro-2-propanol (HFIP). The infrared spectra of polymer films (cast from $CHCl_3$ or HFIP) were recorded on a Beckman Acculab 1 spectrophotometer. The NMR spectra of the polymer solutions in $CHCl_3$ were recorded on an MH-100 or CFT-20 spectrophotometer. A DuPont 990 DSC apparatus was used to record the glass transition (T_g), crystallization (T_c) and melting (T_m) temperatures of the polymers under nitrogen, using about 5 mg samples and a heating rate of 10° C./min. or as otherwise specified. The thermogravimetric analysis (TGA) data of the polymers were recorded under nitrogen using a DuPont 950 TGA apparatus and a heating rate of 10° or 20° C./min. with about 10 mg samples. A Philips vertical goniometer with graphite crystal monochromatized copper K_α radiation was used to obtain the X-ray powder and fiber diffraction patterns of the polymers. Crystallinity was determined by the method of Hermans and Weidinger and the diffractometer patterns were resolved with a DuPont 310 curve analyzer.

In vitro hydrolysis of polymer discs (about 1.2 g, 2.2 cm diameter) and monofilaments (7-25 mil) was conducted at 37° C. in phosphate buffer comprising a solution of 27.6 g sodium dihydrogenphosphate monohydrate in 1000 ml. water adjusted to pH 7.25 with sodium hydroxide.

In vivo absorption (muscle) was determined by implanting two 2 cm segments of monofilament fiber into the left gluteal muscles of female Long Evans rats. The implant sites were recovered after periods of 60, 90, 120

180 days and examined microscopically to deter- the extent of absorption. In vivo absorption (sub- ,eous) is a non-histological technique in which .nuous observation of the biological degradation of ents of suture is made by implanting two segments iture, 2 cm long, into the abdominal subcutis of ıg female rats. The implants are readily visible n the skin is wetted with propylene glycol and ıt of absorption can be determined by subjective ıl examination.

vivo strength retention was determined by im- ting segments of sutures in the posterior dorsal utis of female Long Evans rats for period of 5 to 30 . The sutures were recovered at the designated ds and pull-tested for straight tensile strength.

vitro strength retention was determined by placing nents of sutures in the afore-defined buffer at 50° C. periods of 2 to 4 days. The sutures were recovered he designated periods and pull-tested for straight ile strength.

EXAMPLES

General Polymerization Procedure

iethyl oxalate was heated with selected diols in a hanically-stirred reactor using a stannous alkanoate organic titanate catalyst. The reaction was con- ted under a nitrogen atmosphere at suitable temper- es until a substantial portion of the calculated ount of ethanol was obtained. Postpolymerization of resulting prepolymer was then continued under uced pressure using a suitable heating scheme. At end of the postpolymerization period, the molten ymer was allowed to cool slowly at room tempera- e, isolated, ground and dried at 25° C. to 80° C. (de- ding on the polymer T_m) in vacuo for at least one . Alternatively, the prepolymer can be postpolymer- d partially in the liquid state, cooled, and then post- ymerized further in the solid state as finely divided ticles. Detailed experimental conditions for the prep- ation of representative samples of isomorphic polyox- tes and important properties of the resulting poly- rs are presented below.

EXAMPLE I

95/5 Poly (trans 1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate)

Distilled diethyl oxalate (19.0 g, 0.130 mol), recrystal- ed trans 1,4-cyclohexanedimethanol (19.8 g, 0.137 ol), 1,6-hexadiol (0.856 g, 0.00724 mol) and stannous ctoate (0.33 M in toluene; 0.080 ml, 0.026 mmol) were dded under dry and oxygen-free conditions to a glass actor equipped for magnetic stirring. The prepolymer as formed by heating the mixture at 120° C. for 3 ours under nitrogen at 1 atmosphere while allowing e formed ethanol to distill, followed by heating at 60° C. for 2 hours. The prepolymer was then heated in acuo (0.05 mm Hg) at 220° C. for 1 hour, and the ostpolymerization completed by heating at 215° C. for n additional 6 hours. The polymer was then allowed to ool to room temperature, isolated and ground, and inally dried in vacuo at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.50

DSC (20° C./min.): T_m = 210° C.

Polymer Melt-Spinning:

The polymer was spun using an Instron Rheometer with a 30 mil die at 207° C.

In Vitro Evaluation:

The undrawn fibers lost 21 and 66 percent of their initial mass after immersion in phosphate buffer at 37° C. for 42 and 127 days, respectively.

EXAMPLE II

85/15 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (58.4 g, 0.400 mols), recrys- tallized trans 1,4-cyclohexanedimethanol (less than 1% cis isomer; 53.9 g, 0.374 mols), 1,6-hexanediol (7.8 g, 0.066 mol), and stannous octoate (0.33M in toluene; 0.40 ml, 0.13 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for mechanical stirring. The mixture was heated at 120° and 150° C. for 2 and 3 hours, respectively, under nitrogen at one atmo- sphere while the formed ethanol distilled. The prepoly- mer was allowed to cool, then reheated to 200° C. under reduced pressure (0.1 mm Hg). Temperatures of 200°, 220° and 230° C. were maintained for 2, 3 and 4 hours while the collection of distillates continued. The result- ing polymer (ηinh in $CHCl_3$ = 0.49) was cooled, iso- lated, ground (2 mm screen size), and then dried in vacuo at room temperature. Portions (30 g) of this ground polymer were postpolymerized in the solid state in glass reactors equipped for magnetic stirring by heat- ing in vacuo (0.1 mm Hg) at 185° C. for 22 hours.

Polymer-Characterization:

ηinh in $CHCl_3$ = 1.14

DSC (20° C./min.): T_m = 187° C.

Polymer Melt-Spinning:

The polymer was spun at 230° C. using an Instron Rheometer with a 40 mil die. The fiber was quenched in ice water, wound, dried and subsequently drawn.

Fiber Properties:

Fibers drawn 5X in two stages, 4X at 62° C. followed by 1.25X at 119° C. exhibited the following properties: diameter = 8.5 mils, straight tensile strength = 8.39 × 10^4 psi; knot tensile strength = 5.06 × 10^4 psi; modulus = 6.61 × 10^5 psi; elongation = 15%.

In Vivo Evaluation:

Sterilized (via γ-radiation, 2.5 Mrads), drawn mono- filament (8.5 mils) retained 89, 75, 10 and zero percent of its initial breaking strength (4.8 lbs.) after subcutane- ous implantation in rat muscle for 3, 7, 14 and 21 days respectively. Drawn filaments implanted into the glu- teal muscles of rats elicited median tissue responses in the slight range throughout a 180 day post-implantation period. Filaments drawn 4X at 60° C. followed by 1.25X at 110° C. and having a straight tensile of 6.76 × 10^4 psi showed indications of initial degradation 20 to 26 weeks after implantation.

In Vitro Evaluation:

Fibers drawn 4X at 60° C. (exhibiting a straight ten- sile of 4.33 × 10^4 psi) lost 40 percent of their initial mass after immersion in phosphate buffer at 37° C. for 84 days.

EXAMPLE III

80/20 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (43.8 g, 0.300 mol), recrystal- lized trans 1,4-cyclohexanedimethanol (cis isomer con-

tent = 1.0%, 36.3 g, 0.252 mol), 1,6-hexanediol (7.4 g, 0.063 mol), and stannous oxalate (12.4 mg., 0.060 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for mechanical stirring. The prepolymer was formed by heating the mixture at 120° C. for 2 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill, followed by 160° C. for 2.5 hours. The mixture was allowed to cool, then reheated in vacuo (0.1 mm Hg) to 140° C. and maintained until the prepolymer melted. The temperature was then increased to 190° C., maintained for 30 minutes, then raised to 200° C. for 1.5 hours. The melt post-polymerization of the stirred polymer was completed by heating at 220° C. for 4.5 hours. The polymer was cooled, isolated, ground (screen size = 2 mm) and dried in vacuo at room temperature. To obtain the final product, the ground polymer was post-polymerized in the solid state in a glass reactor equipped for magnetic stirring by heating at 180° C. in vacuo (0.05 mm Hg) for 24 hours while allowing the formed diols to distill.

Polymer Characterization:

ηinh in $CHCl_3$ = 1.33

DSC (20° C./min.): T_m = 205° C.

Polymer Melt-Spinning:

The polymer was spun at 240° C. using an Instron Rheometer equipped with a 40 mil die. The extruded filaments were quenched in ice water, wound, then dried at room temperature in vacuo, and subsequently drawn 4X.

Fiber Properties:

Diameter = 9.0 mils; straight tensile strength = 7.31 $\times 10^4$ psi; knot tensile strength = 3.46 $\times 10^4$ psi; modulus = 7.7 $\times 10^5$ psi; elongation = 15%.

In Vivo Evaluation:

Sterilized (by γ-radiation, 2.5 Mrads), fibers (9.0 mil) retained 85, 20 and zero percent of their initial breaking strength (4.2 lbs.) after subcutaneous implantation in rat muscles for 3, 7 and 14 days, respectively. These fibers were also implanted into the gluteal muscles of rats to determine tissue response and absorption characteristics. The median tissue response elicited by the samples was in the slight range after 5 days post implantation and in the minimal range after 42 days; absorption of the samples was first noted at 120 days and by 180 days approximately fifty percent of the material had been absorbed.

EXAMPLE IV

80/20 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (23.4 g, 0.160 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer content = 6.3%; 20.0 g, 0.139 mol), 1,6-hexandiol (4.1 g, 0.035 mol) and Tyzor OG* (0.117M in toluene, 0.28 ml, 0.033 mmols) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. A prepolymer was formed by heating the mixture at 120° C. for 19 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill. The pressure was then reduced (0.05 mm Hg) and heating at 120° C. continued for 30 minutes longer. The temperature was then increased and maintained at 180° C., 190° C. and 200° C. for 2, 5 and 2 hours, respectively, while removing excess and formed diols. The polymer was allowed to cool, isolated, ground, and dried in vacuo at room temperature.

*Tyzor OG, a titanium glycolate catalyst manufactured by E. I. DuPont de Nemours and Co., Wilmington, Del., 19898

Polymer Characterization:

ηinh in $CHCl_3$ = 0.46

DSC (10° C./min.): T_m = 171° C.

TGA (10° C./min. under N_2): 0.25% weight lost at 275° C.

Polymer Melt-Spinning:

The polymer was spun using an Instron Rheometer with a 30 mil die at 172° C. The extruded filaments were quenched in ice water, dried in vacuo at room temperature, and finally drawn 5X at 43° C.

Fiber Properties:

ηinh in $CHCl_3$ = 0.42

X-ray: Major reflections correspond to 8.9 (W), 4.84 (M), 4.41 (S) and 3.42Å (W) d-spacings; 26% crystallinity. (Undrawn filaments were found to be 22% crystalline which increased to 31% by annealing at 70° C. for one hour).

Physical Properties:

Diameter = 11.1 mils; straight tensile strength = 2.07 $\times 10^4$ psi; elongation = 35%.

In Vivo Evaluation:

The rate of absorption and tissue response of drawn filaments was determined by implantation into the ventral abdominal subcutis of Long-Evans rats. Some evidence of filament degradation was noted 11 to 14 weeks after implantation, with the bulk of the fiber being absorbed by 20 to 23 weeks. No tissue reaction to the implants was noted at any period.

In Vitro Evaluation:

The drawn fibers exhibited a 43% decrease in mass after immersion in the phosphate buffer at 37° C. for 28 days.

EXAMPLE V

67/33 Poly(trans 1,4-cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (40.0 g, 0.274 mol), recrystallized trans 1,4-cyclohexanedimethanol (25.9 g, 0.180 mol), 1,6-hexanediol (10.6 g, 0.0897 mol), and stannous octoate (0.33 M in toluene; 0.16 ml, 0.053 mmol) was added to a glass reactor equipped for mechanical stirring. The prepolymer was formed by heating the mixture under nitrogen at 120° C. for 9 hours, followed by 125° C. for 9 hours while collecting the distillates. The prepolymer was cooled, then reheated in vacuo (0.03 mm Hg) and maintained at 80, 120, 150, 170 and 180° C. for 1, 2, 2, 3 and 1.5 hours, respectively. The postpolymerization of the polymer melt was completed by heating at 195° C. for 6 hours while continuing to stir and remove distillates. The polymer was cooled, isolated, ground, and then dried at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.49

DSC (20° C./min.): T_m = 179° C.

Polymer Melt Spinning:

The polymer was spun at 175° C. using an Instron Rheometer with a 30 mil die. The resulting fibers were subsequently drawn 4X at 50° C.

Fiber Properties:

Diameter = 9.3 mils, straight tensile strength = 2.65 $\times 10^4$ psi, knot tensile strength = 2.21 $\times 10^4$ psi, modulus = 3.7 $\times 10^5$ psi.

In Vivo Evaluation, Tissue Reaction:

Two centimeter long samples of sterilized (by γ-radiation, 2.5 Mrads) drawn fiber were implanted sub-

cutaneously in the abdominal wall of young female Long Evans strain rats. At intervals of 3, 14, 28, 56 and 90 days, two rats were sacrificed for examination of implants. The skin containing the fibers was excised and affixed to plastic sheets for preservation in formalin. Two tissue blocks were cut transversely from each site and embedded in paraffin for histologic preparation. Eight stained samples were examined at each interval for tissue reaction to the fibers. Only mild foreign body reactions were detected.

In Vivo Evaluation, Absorption:

Fiber segments sterilized by γ-radiation (2.5 Mrads) approximately 2 cm in length were inserted into the ventral abdominal subcutis of Long Evans rats (100 g, female) to determine the rate of absorption of the drawn fibers. One to two rats were sacrificed after various periods after implantation. The skin containing the implant sites was removed and dried. These preparations were examined and evaluated using both dissecting and transmission microscopes. Estimates of the amount of implant remaining were based on the length of the segment or fragments remaining and the decrease in the surface area made by palpating the implant in the dried hide and comparing it with a one week old preparation. Implants were fragmented at one week; migration and clumping of fragments was noted at subsequent kill periods. Evidence of degradation was first seen 16 weeks after implantation. Palpable fragments, in diminishing amounts, were present until 30 weeks. Quantitatively, about 100, 75, 45, 40, 20, 15 and 5 or less percent of the suture remained after 14, 16, 20, 23, 26, 30 and 36 weeks.

EXAMPLE VI

50/50 Poly (trans 1,4-cyclohexyldicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (38.0 g, 0.260 mol), recrystallized trans 1,4-cyclohexanedimethanol (20.2 g, 0.140 mol), 1,6-hexanediol (16.5 g, 0.140 mol), and stannous octoate (0.33 M in toluene, 0.16 ml, 0.053 mmol) were added under dry and oxygen-free conditions to a mechanically stirred glass reactor. Under nitrogen at one atmosphere, the mixture was heated to and maintained at 120° C. for 20 hours, while allowing the formed ethanol to distill. The prepolymer was cooled and then reheated in vacuo (0.05 mm Hg) to and maintained at 80°, 120°, 140°, 165°, 175°, 185°, and 195° C. for 1, 1, 3, 3.5, 2, 1 and 1 hour respectively. The removal of the diols was continued by heating at 200° C. for 8 hours to complete the postpolymerization. The polymer was cooled, isolated, ground, and then dried in vacuo at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.36

DSC (20° C./min.): T_m = 138° C.

Polymer Melt Spinning:

The polymer was spun at 136° C. using an Instron Rheometer (40 mil die) and was immediately drawn 5X at 53° C.

Fiber Properties:

X-ray Data: Major reflections correspond to 8.9 (W), 4.84 (M), 4.41 (S), and 5.40 Å (W) d-spacings; 36% crystallinity.

Physical Properties: Diameter = 10.6 mils, straight tensile strength = 1.36 × 10^4 psi, knot tensile strength = 1.13 × 10^4 psi, modulus = 1.33 × 10^5 psi, elongation = 27%.

In Vivo Evaluation:

Sterilized (by γ-radiation) drawn fiber segments (2 centimeters in length) were implanted into the ventral abdominal subcutis for study of the rate of absorption and tissue reaction.

At one week the implants were fragmented, clumping, and migrating, with the bulk of the suture being absorbed between 6 to 11 weeks. Thereafter, fragments with scattered birefringent particles or birefringent particles in a shell-like outline were observed. The birefringent particles decreased in amount until at 36 weeks only a few widely scattered particles were noted.

Only mild foreign body reactions were observed to be elicited by the sterilized drawn fiber segments during the test intervals of 3, 14, 28, 48, 90 and 180 day post implantation.

In Vitro Evaluation:

Undrawn fibers exhibited a 57 percent decrease in their initial mass after immersion in phosphate buffer at 37° C. for 28 days.

EXAMPLE VII

50/50 Poly (trans 1,4-cyclohexyldicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (58.5 g, 0.400 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer content = 0.7%; 29.7 g, 0.206 mol), 1,6-hexanediol (24.3 g, 0.206 mol), and stannous oxalate (16.5 mg, 0.080 mmols), were added under dry and oxygen-free conditions to a mechanically stirred glass reactor. The mixture was heated under nitrogen at one atmosphere to and maintained at 120° and 160° C. for 3 and 2 hours respectively while allowing the formed ethanol to distill. The propolymer was cooled and then reheated in vacuo (0.05 mm Hg) and maintained at 170°, 190° and 205° C. for 3, 2.5 and 3 hours respectively while continuing to remove excess and formed diol to complete the postpolymerization. The polymer was cooled, isolated, ground, and then dried in vacuo at room temperature.

Polymer Characterization:

ηinh in HFIP = 1.07

DSC (20° C./min.) T_m = 132° C.

Polymer Melt Spinning:

The polymer was spun at 150° C. using an Instron Rheometer (40 mil die) and was drawn 4X at 50° C. followed by 1.5X at 72° C.

Fiber Properties:

X-ray Data: Major reflections correspond to 9.11 (MS), 4.82 (S), 4.60 (W), 4.37 (S) and 3.45 Å (W) d-spacings; 46% crystallinity.

Physical Properties: Diameter = 7.6 straight tensile strength = 51,300 psi, knot tensile strength = 36,400 psi, elongation = 31%.

EXAMPLE VIII

30/70 Poly (trans 1,4-cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (36.5 g, 0.250 mol), recrystallized trans 1,4-cyclohexanedimethanol (11.5 g, 0.0797 mol), 1,6 hexanediol (22.4 g, 0.190 mol), and stannous octoate (0.33 M in toluene; 0.16 ml, 0.053 mmol) were added under dry and oxygen-free conditions to a mechanically stirred reactor. The mixture was heated to and maintained at 125°, 140° and 160° C. for 2, 2 and 1 hour, respectively, under nitrogen at one atmosphere

while allowing the formed ethanol to distill. The prepolymer was cooled and then reheated in vacuo (0.1 mm Hg) and maintained at 150° and 185° C. for 16 and 3 hours, respectively. The postpolymerization was completed by maintaining the polymer at 200° C. for 5.5 hours while continuing to remove the diols under vacuum. The polymer was then cooled, isolated, ground and dried in vacuo at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.82

DSC (20° C./min): T_m = 85° C.

Polymer Melt Spinning:

The polymer was spun at 125° C. using an Instron Rheometer with a 40 mil die. The fiber was quenched in ice water, wound, dried in vacuo at room temprature, and subsequently drawn 5.6X at room temperature, followed by annealing at 55° C.

Fiber Properties:

Diameter 8.3 mils, straight tensile strength 5.18 × 10^4 psi, knot tensile strength 3.51 × 10^4 psi, modulus 2.11 × 10^5 and elongation 50%.

In Vivo Evaluation:

Sterilized (by γ-radiation, 2.5 Mrads), drawn fibers (9.8 mil diameter; 3.64 × 10^4 psi straight tensile strength; 2.34 × 10^4 psi knot tensile strength; 1.47 × 10^5 psi modulus; and an elongation of 45%) were implanted into the gluteal muscles of rats to determine their absorption and tissue response characteristics at 5, 21, 42 and 150 days post implantation.

At the 42 day period, there was no evidence of any morphologic changes of the implant sites indicating absorption. At the 150 day period, the fibers had a median value of 2 percent suture cross sectional area remaining (with a range of 0 to 20 percent).

Foreign body tissue responses to the samples were in the slight range at 5, 21 and 42 day periods and in the minimal range at the 150 day period.

In Vitro Evaluation:

Drawn fibers possessing physical properties similar to those of fibers used in the in vivo testing exhibited a 100% decrease in their initial mass after 141 days of immersion in phosphate buffer at 37° C.

EXAMPLE IX

5/95 Poly (trans 1,4-cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (19.0 g, 0.130 mol), recrystallized trans 1,4-cyclohexanedimethanol (1.0 g, 0.0069 mol), 1,6-hexanediol (16.3 g, 0.138 mol), and stannous octoate (0.33 M in toluene; 0.08 ml, 0.026 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. The prepolymer was formed by heating the mixture at 120° C. for 3 hours under nitrogen at one atmosphere while allowing the formed ethanol to distill, followed by 160° C. for 2 hours. The prepolymer was heated and maintained at 205° C. for 8 hours in vacuo (0.05 mm Hg). The polymer was then cooled, isolated, ground, and dried at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.98

DSC (20° C./min): T_m = 69° C.

TGA (20° C./min. under N_2): Less than 0.5% weight loss at 275° C. was recorded.

Polymer Melt Spinning:

The polymer was spun in an Instron Rheometer using 30 mil die at 85° C. The fibers were quenched in ice water and subsequently drawn 5X at room temperature.

Fiber Properties:

Diameter = 14.7 mils, straight tensile strength = 1.36 × 10^4 psi, knot tensile strength = 1.41 × 10^4 psi, modulus = 4.8 × 10^4 psi, elongation = 90%.

In Vitro Evaluation:

The drawn fibers exhibited a 93 percent decrease in their initial mass after immersion in phosphate buffer at 37° C. for 42 days.

EXAMPLE X

58/42 Poly (1,4-phenylenedicarbinyl-co-hexamethylene Oxalate):

Diethyl oxalate (14.6 g, 0.100 mols), recrystallized 1,4-benzenedimethanol (6.9 g, 0.050 mols), 1,6-hexanediol (8.3 g, 0.070 mols), and Tyzor TOT* catalyst (0.4 ml of a 1% solution) were added under dry and oxygen-free conditions to a glass reactor equipped for stirring. The prepolymer was formed by heating under nitrogen at one atmosphere at 140° C. for 4 hours while allowing the formed ethanol to distill. The mixture was then heated in vacuo (0.1 mm Hg) at 165° C. for 22 hours while continuing to remove distillates. A postpolymerization was conducted at 180°, 190°, and 200° C. for 2, 1 and 4 hours respectively. The polymer was cooled, ground and dried.

*Tyzor TOT, a tetraalkyl titanate catalyst manufactured by E. I. DuPont de Nemours and Co., Wilmington, Delaware, 19898.

Polymer Characterization:

ηinh in HFIP = 0.48

DSC (10° C./min): T_m = 170° C.

TGA (10° C./min in N_2): Less than 1% cummulative weight loss experienced at 250° C.

Polymer Melt Spinning:

The polymer was spun at 166° C. using an Instron Rheometer equipped with a 30 mil die.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 8 and 78 days in phosphate buffer at 37° C. resulted in a loss of 3 and 99 percent of the initial mass, respectively.

EXAMPLE XI

56/44 Poly (1,4-phenylenedicarbinyl-co-hexamethylene Oxalate):

Dibutyl oxalate (20.2 g, 0.100 mols), 1,4-benzenedimethanol (8.3 g, 0.060 mols), 1,6-hexanediol (5.6 g, 0.047 mols), and tetraisopropylorthotitanate catalyst (0.3 ml, of a 0.01M solution) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. The prepolymer was formed by heating at 140°, and 160° C. for 1, and 17 hours respectively under nitrogen at one atmosphere while allowing the formed butanol to distill. The pressure was reduced (0.2 mm Hg) while continuing to heat at 160° C. for an additional hour. The postpolymerization of the polymer melt was completed by heating at 180° C. and 200° C. for 2, and 3.5 hours, respectively, while continuing to remove distillates. The polymer was cooled, and isolated.

Polymer Characterization:

ηinh in HFIP = 0.42

DSC (10° C./min): T_m = 165° C.

TGA (10° C./min in N_2): Less than 1% cummulative weight loss experienced at 250° C.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 7 and 77 days, in phosphate buffer at 37° C. resulted in a loss of 3 and 56 percent of the initial mass, respectively.

EXAMPLE XII

50/50 Poly (1,4-phenylenedicarbinyl-co-hexamethylene Oxalate):

In a manner similar to that employed in Examples X and XI, the above identified copolymer having the following characteristics was produced:

DSC (10° C./min): $T_m = 175°$ C.

TGA (10° C./min, in N_2): Less than 1% cummulative weight loss experienced at 250° C.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 8 and 78 days in phosphate buffer at 37° C. resulted in a loss of 6 and 54 percent of the initial mass, respectively.

While the preceding examples have been directed to the preparation of specific copolymers of polyoxalates, these examples are for purposes of illustration only and are not limiting of the invention. Mixtures of these polymers and combinations of these polymers with up to about 50 percent by weight of poly (alkylene oxalates) and other compatible polymers which produce non-toxic and absorbable polymers are likewise included within the present invention.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the sutures. As used herein, the term "inert" means materials that are chemically inert to the polymer and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis-2-methoxyehtyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments of the present invention even more pliable, it also serves as a processing aid in extrusion and thread preparation.

Filaments of the present invention are adversely affected by moisture and are accordingly preferably stored in hermetically sealed and substantially moisture-free packages, a preferred form of which is shown in FIG. 2. In FIG. 2, there is shown a suture package 14 having disposed therein a coil of suture 12, one end of which is attached to needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or filled with a dry atmosphere of air or nitrogen. The illustrated package is fabricated of two sheets of aluminum foil or an aluminum foil-plastic laminate and heat sealed or bonded with adhesive at the skirt 16 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

Filaments of the present invention may be used as monofilament or multifilament sutures, or may be woven, braided, or knitted either alone or in combination with other absorbable fibers such as poly (alkylene oxalate), polyglycolide or poly (lactide-co-glycolide), or with nonabsorbable fibers such as nylon, polypropylene, polyethylene-terephthalate, or polytetrafluoroethylene to form multifilament sutures and tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like.

Multifilament yarns that contain isomorphic copolyoxalate filaments of the present invention together with nonabsorbable filaments are illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross-section 19. In FIG. 4, the fibers 20 are extruded from polymer compositions of the present invention as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants.

Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting and nonwoven felting are described in U.S. Pat. Nos. 3,108,357 and 3,463,158. Methods of weaving and crimping tubular vascular prostheses are described in U.S. Pat. No. 3,096,560. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of the polymers of this invention. The surgical utility of "bi-component filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158 the teaching of which is incorporated herein by reference. Monofilaments of the polymers of the present invention may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney and other internal organs.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws as illustrated in FIG. 3, reinforcing plates, etc., may be machined from solid polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

Many different embodiments of this invention will be apparent to those skilled in the art and may be made without departing from the spirit and scope thereof. It is accordingly understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

We claim:

1. A synthetic absorbable suture of oriented fiber comprising an isomorphic polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula

$$\left[-O-R-O-\overset{\overset{O}{\|}}{C}-\overset{\overset{O}{\|}}{C}- \right]_x$$

wherein each R is

$$-(CH_2)_n-A-(CH_2)_n- \qquad \text{I}$$

or

$$-(CH_2)_{4+2n}- \qquad \text{II}$$

and from about 5 to 95 mol percent of the R units are I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

2. A suture of claim 1 wherein said fiber is a monofilament.

3. A suture of claim 1 wherein said fiber is a multifilament.

4. A suture of claim 3 wherein said multifilament fiber is a braid.

5. A suture of claim 1 wherein n is 1 and A is trans 1,4-cyclohexylene.

6. A suture of claim 1 wherein n is 2 and A is trans 1,4-cyclohexylene.

7. A suture of claim 5 wherein from about 40 to 75 mol percent of the R units are of formula I.

8. A suture of claim 1 wherein n is 1 and A is p-phenylene.

9. A suture of claim 1 wherein n is 2 and A is p-phenylene.

10. A suture of claim 1 having a surgical needle attached to at least one end thereof.

11. A suture of claim 10 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

12. The method of closing a wound in living tissue which comprises approximating the wound tissue with an absorbable suture comprising of sterile, oriented fiber comprising an isomorphic copolyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula

$$\left[O-R-O-\overset{O}{\overset{\|}{C}}-\overset{O}{\overset{\|}{C}} \right]_x$$

wherein each R is

$$-(CH_2)_n-A-(CH_2)_n- \qquad \text{I}$$

or

$$-(CH_2)_{4+2n}- \qquad \text{II}$$

with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

13. The method of claim 12 wherein said fiber is a monofilament.

14. The method of claim 12 wherein said fiber is a multifilament.

15. The method of claim 14 wherein said multifilament fiber is a braid.

16. The method of claim 12 wherein n is 1 and A is trans 1,4-cyclohexylene.

17. The method of claim 12 wherein n is 2 and A is trans 1,4-cyclohexylene.

18. The method of claim 16 wherein units of formula I comprise from 40 to 75 mol percent of the R groups.

19. The method of claim 12 wherein A is p-phenylene.

20. A surgical prosthesis of a fabric manufactured at least in part from synthetic absorbable fibers comprising an isomorphic polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula:

$$\left[O-R-O-\overset{O}{\overset{\|}{C}}-\overset{O}{\overset{\|}{C}} \right]_x$$

wherein each R is

$$-(CH_2)_n-A-(CH_2)_n- \qquad \text{I}$$

or

$$-(CH_2)_{4+2n}- \qquad \text{II}$$

with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

21. A surgical prosthesis of a solid surgical aid cast or machined from an absorbable polymer comprising an isomorphic polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula

$$\left[O-R-O-\overset{O}{\overset{\|}{C}}-\overset{O}{\overset{\|}{C}} \right]_x$$

wherein each R is

$$-(CH_2)_n-A-(CH_2)_n- \qquad \text{I}$$

or

$$-(CH_2)_{4+2n}- \qquad \text{II}$$

with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2, and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

* * * * *

United States Patent [19] [11] Patent Number: 4,959,069
Brennan et al. [45] Date of Patent: Sep. 25, 1990

[54] BRAIDED SURGICAL SUTURES

[75] Inventors: Karl W. Brennan, Somerset; Alison M. Skinner, Long Valley, both of N.J.; Gregory Weaver, New Hope, Pa.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 424,622

[22] Filed: Oct. 20, 1989

[51] Int. Cl.[5] A61B 17/00
[52] U.S. Cl. 606/228; 428/224; 87/7
[58] Field of Search 606/228, 229, 230, 231, 606/151; 138/123, 129; 139/317; 428/224

[56] References Cited

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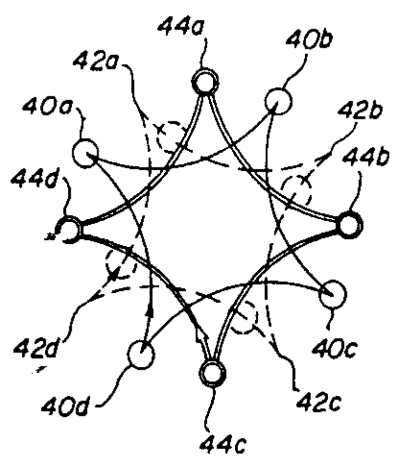
Primary Examiner—Randall L. Green
Assistant Examiner—Gary Jackson

[57] ABSTRACT

A braided surgical suture is provided which in a first embodiment is woven in a spiral braid. The suture is braided by moving thread carriers from position to position around a circular path. As each carrier moves it moves from its present position to a succeeding position which is at least two positions removed from its present position. Such spiral braided sutures are advantageously produced without core filaments, providing benefits in strength, smoothness, pliability and cylindrical uniformity without the discontinuity of properties characteristic of conventionally braided cored sutures. In a second embodiment the suture is woven in a lattice braid, providing a plurality of distributed core passageways for individual core fibers.

17 Claims, 4 Drawing Sheets



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000308

FIG-1a

PRIOR ART

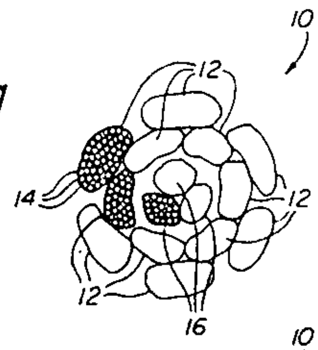


FIG-1b

PRIOR ART

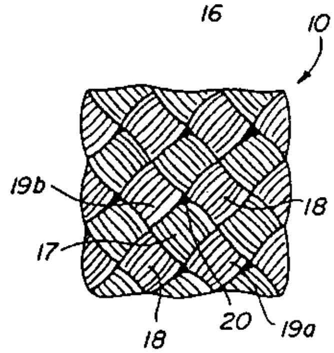


FIG-3

PRIOR ART

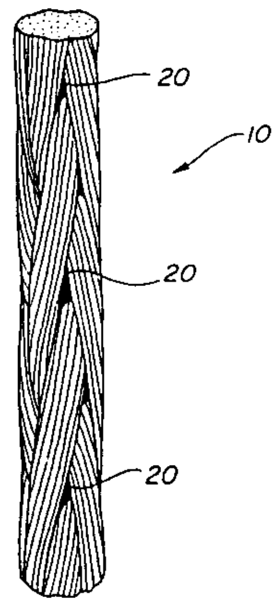


FIG-2 PRIOR ART

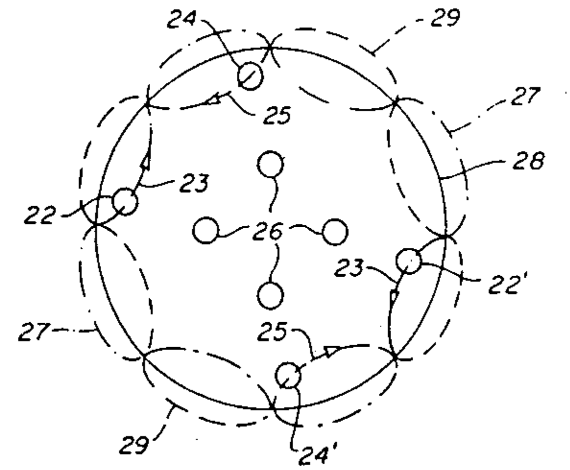


FIG-4a

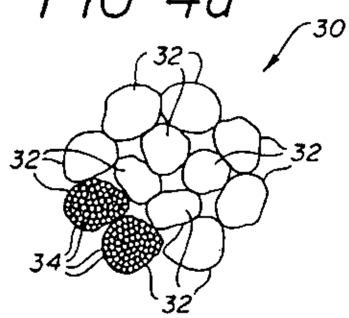


FIG-4b

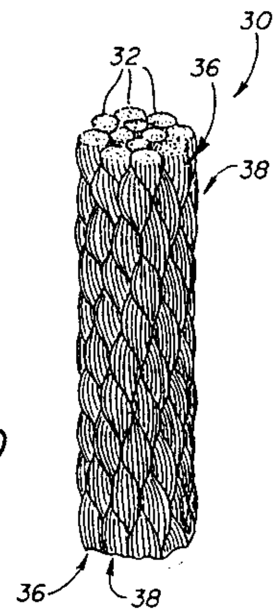


FIG-5a

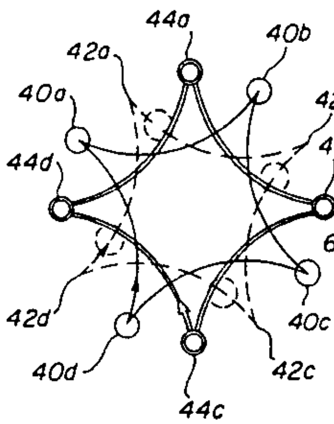


FIG-5b

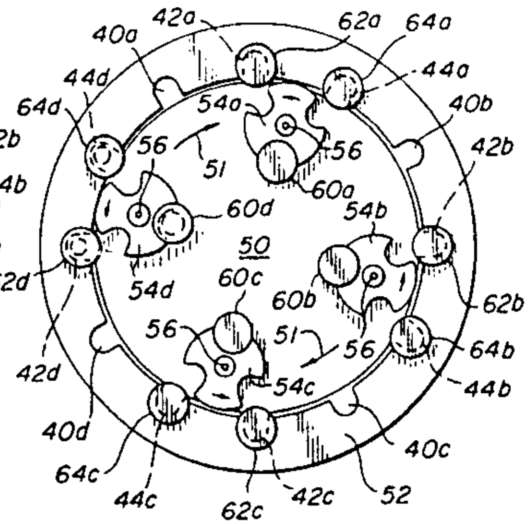


FIG-6a

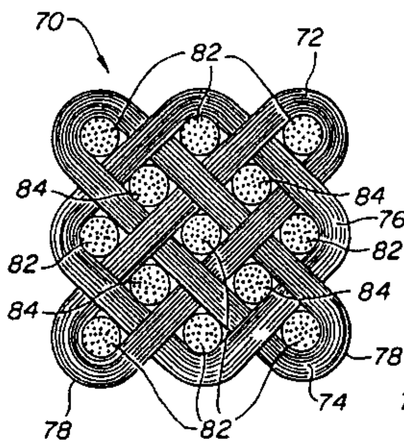


FIG-6b

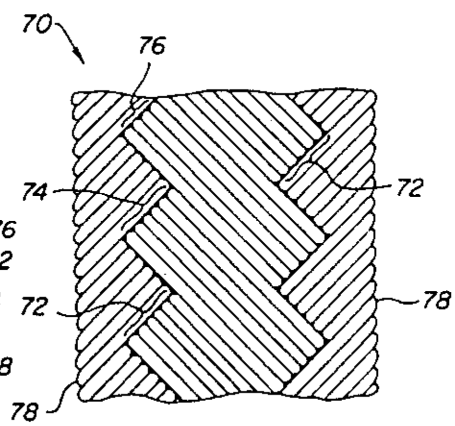
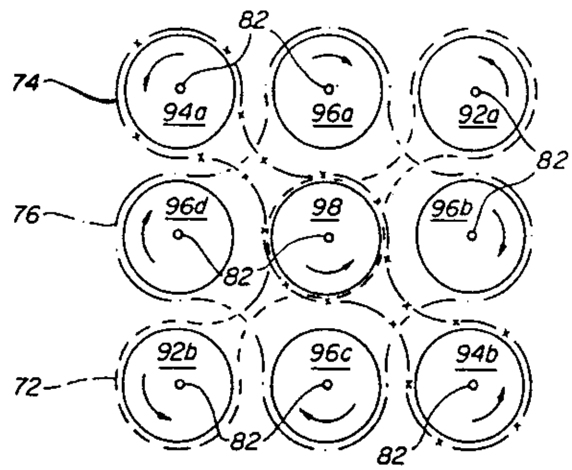


FIG-7



BRAIDED SURGICAL SUTURES

This invention relates to surgical sutures and, in particular, to braided surgical sutures which obviate the need for a central fiber core.

Surgical sutures may be manufactured in two general forms: monofilaments and multifilaments. Monofilament sutures are generally made of natural materials such as gut, or of extruded polymeric materials such as Nylon, polypropylene, or poly (p-dioxanone), and are highly regarded for their uniform, smooth construction and uniformly distributed tensile strength. However, monofilament sutures generally have the drawback of being fairly rigid and lacking pliability. Multifilament sutures consisting of a plurality of braided filaments of a fine gauge have been found to provide the characteristic of pliability which is often desired by surgeons Such braided sutures may be made of poly(lactide-co-glycolide), polyglycolide, polyester, or silk, for example. But since braided sutures often lack substantial tensile strength, the braided filaments are conventionally braided in a tubular sheath around a core of longitudinally extending threads. Such braided sheath sutures with central cores are shown in U.S. Pat. No. 3,187,752; 4,043,344; and 4,047,533, for example.

Braided sutures with central core threads have been found to exhibit certain disadvantages, however. One is that the tensile strength of the suture is not evenly distributed between the braided sheath and the central core threads. As a consequence, when these sutures are stretched, the sheath and the core will respond differently to the application of the tensile forces. The sheath will respond to the forces independently of the central core threads, causing the central threads to move longitudinally relative to the surrounding sheath. The core threads can also flatten and redistribute themselves within the sheath instead of maintaining the desired rounded cross-sectional shape of the suture. It would be desirable for such tensile forces to be more uniformly distributed throughout the suture, so that all of the fibers of the suture will respond in unison to the tensile forces without distortion of the normal shape of the suture.

Conventionally braided sutures can also feel rough to the touch, due to the changing crossing pattern of the braided filaments, and the interstices formed where the braided fibers overlap and cross each other. To minimize this tactile characteristic it is often necessary to further process the braided suture by heating and stretching the suture. Furthermore, such interstices can trap and retain moisture in a wicking fashion. Retained moisture has been found to be a source of undesired deterioration of sutures made of certain materials, such as absorbable sutures made of poly(lactide-co-glycolide) or polyglycolide, and can also lead to retention of sources of infection within the braid. It would be desirable to form braided sutures which are smoother to the touch, and which do not exhibit interstices or passageways which can trap and retain moisture prior to use of the sutures.

It would further be desirable for braided sutures to match or exceed the breaking strength characteristics of presently available braided sutures with central core threads.

In accordance with the principles of the present invention, a braided suture is provided in which the filaments or threads are braided in a spiral pattern. Sutures

braided in a spiral pattern have been found to be capable of maintaining a uniformly rounded cross-sectional shape, and to distribute tensile forces uniformly throughout the braided fibers. Spiral braided sutures also do not form the tube-like structure of the conventional braiding pattern, which eliminates the need for a central fiber core. Since spiral braiding results in an outer sheath pattern in which the braided threads are all flowing in the same direction, the suture is much smoother to the touch than the conventionally braided suture. The smoothly flowing braided configuration also does not provide interstices which can trap undesired moisture in the suture. Furthermore, the spiral braided suture has been found to be stronger, smoother to the touch, and much more pliable than the conventionally braided suture.

In accordance with a further aspect of the present invention a suture is provided which is formed by lattice braiding. The lattice braided suture exhibits a plurality of interwoven threads in a generally rectangular cross-sectional configuration. The lattice braid may be woven around a plurality of core threads distributed in the internal interstices of the lattice network and interlocked into position, unlike the central bundle of core threads of the conventionally braided suture. The lattice braided suture has been found to be superior to the conventionally braided core suture in that it does not exhibit "core pop", the tendency of the core filaments to break through the braided sheath as the suture is bent.

In the drawings:

FIGS. 1*a* and 1*b* illustrate diagrammatic cross-sectional and side views of a conventionally braided suture;

FIG. 2 illustrates the braiding pattern of a conventionally braided suture;

FIG. 3 is a drawing of an enlarged view of the outer sheath of a conventionally braided suture;

FIGS. 4*a* and 4*b* illustrate diagrammatic cross-sectional and side views of a spiral braided suture of the present invention;

FIG. 5*a* illustrates the braiding pattern of a spiral braided suture of the present invention;

FIG. 5*b* is a diagrammatic plan view of a mechanism used to braid a spiral braided suture of the present invention;

FIGS. 6*a* and 6*b* illustrate the braiding pattern and outside sheath of a lattice braided suture of the present invention; and

FIG. 7 is a diagrammatic plan view of a mechanism used to braid a lattice braided suture of the present invention.

Referring first to FIGURE 1*a*, a conventionally braided suture 10 is shown in diagrammatic cross-section. The suture 10 comprises a plurality of threads or carriers 12 which are interwoven to form the braided sheath. Each thread generally comprises a number of individual fibers 14. The braided threads 12 form a tubular sheath around the central core threads 16, which extend longitudinally through the tubular sheath. The sheath is braided using at least three threads, or a greater even number of threads, such as 4, 6, 8, etc. The core may comprise one or any greater number of threads. The suture 10 is shown in FIG. 1*a* to exhibit its desired cylindrical uniformity. However, it has been found that during handling, heating and stretching of the suture during manufacture the tubular sheath can distort to an oval or oblong shape, with the core threads

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000313

16 redistributed in the sheath in an irregular or linear configuration.

As a consequence of the structural independence of the braided sheath and the core threads, the sheath and core will unevenly distribute tensile forces among these two substructures when the suture is stretched, causing the two to move relative to each other. The relative movement of the two can result in the formation of spaces or pockets inside the sheath, between threads 16 of the core and the surrounding sheath. These spaces can entrap moisture through the mechanism of wicking, resulting in premature deterioration and weakening of the suture in in vivo use of the suture.

The conventionally braided suture is woven as indicated by the braiding pattern of FIG. 2, shown in a plan view. The individual threads of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction. In the illustrated embodiment carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. Disposed within the center of the loop 28 are carriers 26 which dispense the core threads of the suture. Thus, the moving carriers 22, 22', 24, and 24' dispense threads which intertwine to form the braided sheath, and the sheath is formed around the centrally located core threads dispensed from carriers 26. The threads from all of the carriers in a constructed embodiment of FIG. 2 are dispensed upward with respect to the plane of the drawing, and the braided suture is taken up on a reel located above the plane of the drawing.

FIG. 1*b* is an illustration of the outside of the braided sheath of the suture 10 of FIG. 1*a*, showing the crossing pattern of the braided threads 12. Each thread is composed a number of individual fibers as indicated by the lines on each thread. Where each thread appears on the outside of the sheath it is seen to be orthogonally directed with respect to the thread it crosses over, the thread from beneath which it appears, and the thread it next crosses under. For instance, thread 17 is orthogonally directed with respect to thread 18 on either side of thread 17 where thread 17 crosses over thread 18. The thread 17 is also orthogonally directed with respect to thread 19*a* from beneath which it appears, and with respect to thread 19*b* which it next crosses under.

This orthogonal crossing relationship of the braided threads results in the formation of small interstices or voids 20 where the threads cross one another, as shown in FIG. 3, which shows a drawing reproduction of an enlarged photograph of a conventionally braided suture. These voids 20 can entrap moisture which can lead to premature deterioration of the suture, and can also entrap bacteria and other sources of infection causing complication of wound healing.

Referring now to FIG. 4*a*, a spiral braided suture 30 of the present invention is shown in diagrammatic cross-section. The braided suture 30 comprises a plurality of interwoven and interlocked threads 32, each of which may comprise a number of individual fibers 34. Due to the interlocking of the threads 32, no central passageway is formed in which moisture can become entrapped. The interlocking of the threads also causes the threads to move in unison as a continuous structure, thereby uniformly distributing tensile forces when the suture 30 is pulled or stretched.

The spiral pattern of the suture 30 is clearly shown in the outside view of the suture of FIG. 4*b*. The threads on the outside are seen to be aligned in a spiral pattern which ascends from the lower left to the upper right in the drawing as the outer threads precess around the outer surface of the suture. One spiraling set of threads is indicated between arrows 36, and another set is indicated between arrows 38. As the pattern spirals, individual threads on the outer surface are in a parallel orientation with respect to each other and with respect to the longitudinal length of the suture as they continually reappear in the spiral pattern.

With all threads aligned in the parallel, offset spiral pattern of FIG. 4*b*, it may be seen that there are no voids or interstices formed on the outside surface of the suture. This is due to the parallel orientation of the threads, as opposed to the orthogonally directed crossing pattern of the threads of the conventionally braided suture of FIGS. 1*b* and 3. The parallel orientation of the outer appearing threads also provides a smoother feel to the suture, since the hand will sense the continuous, longitudinal orientation of the parallel threads as it is run along the suture.

A spiral braided suture of the present invention is formed of four or more interwoven threads. Preferably at least nine threads are braided in groups of three, and a braiding pattern for a spiral braided suture of twelve threads, arranged in groups of four, is shown in FIG. 5*a*. In the illustrated pattern the carriers move sequentially in the same direction around the circular loop of carriers. As they move, each carrier moves from its present position to a succeeding position which is at least two positions removed from its present position. In the illustration of FIG. 5*a*, each carrier moves to the third succeeding position around the loop. The twelve carriers are grouped into three groups of four carriers each. In the first group, carriers move in unison between positions 42*a*, 42*b*, 42*c*, and 42*d*. The carrier at position 42*a* moves to position 42*b*, passing by positions 44*a* and 40*b* as it does so. As it moves, the carrier at position 42*b* is moving to position 42*c*, bypassing positions 44*b* and 40*c*. At the same time the carrier at position 42*c* is moving to position 42*d*, and the carrier at position 42*d* is moving to position 40*a*.

After these four carriers have moved to their new positions in unison, the carriers at positions 44*a*, 44*b*, 44*c*, and 44*b* move to their succeeding positions. Then the carriers at positions 40*b*, 40*c*, 40*d*, and 40*a* move to their succeeding positions. The sequence then repeats in the same fashion.

Apparatus for executing the spiral braiding pattern of FIG. 5*a* is diagrammatically shown in FIG. 5*b*. The apparatus comprises a rotating central platform 50 which is surrounded by an annular plate 52. The platform 50 rotates as indicated by arrows 51. Pivotally mounted on the platform 50 are four rotating carrier pickups 54*a*, 54*b*, 54*c*, and 54*d* which rotate about pivot points 56. Each pickup has a number of apertures which engage the carriers to move them to their succeeding positions, the number being chosen in correspondence with the number of positions to be bypassed as the carriers move in their braiding pattern. In the illustrated embodiment the number of apertures is three, enabling the carriers to bypass two positions each time they are

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000314

moved. The twelve carrier positions are delineated by rounded openings in the annular plate 52, four of which are indicated at 40a, 40b, 40c, and 40d. The carriers which carry spools of thread are indicated at 60, 62, and 64.

In operation pickup 54a will engage the carrier 60a at position 40a. As the central platform 50 rotates the pickup 54a simultaneously rotates to transfer the carrier 60a from position 40a to position 40b, which has just been vacated by carrier 60b. The carrier 60a is seen to bypass carriers 62a and 64a as it travels to its succeeding position 40b. As carrier 60a is transferred by pickup 54a, pickups 54b, 54c, and 54d simultaneously are transferring carriers 60b, 60c, and 60d to their succeeding positions.

As the pickup 54a is about to deposit the carrier 60a at position 40b, the pickup engages carrier 64a to begin transferring that carrier to its succeeding position. The carriers 64b, 64c, and 64d are similarly engaged simultaneously by the other three pickuPs. After the carriers 60a, 60b, 60c, and 60d have been deposited at their new positions and the carriers 64a, 64b, 64c, and 64d are enroute to their succeeding positions, the pickups engage the carriers 62a, 62b, 62c, and 62d for transfer. As this sequence of carrier transfer continues, threads from the spools on the carriers are dispensed upward with respect to the plane of the drawing and the braided suture is taken up on a reel located above the apparatus.

A lattice braided suture 70 of the present invention is shown in FIG. 6a, which schematically illustrates the structure of the lattice braid. In FIG. 6a, three or more threads are braided in a lattice pattern. One thread or group of threads traverses the path 72, a loop extending from the upper right to the lower left of the drawing. As the carrier or carriers dispensing thread on path 72 move around this path, they alternately cross over and under the paths of the other threads that they encounter, the crossing pattern being determined by the times and locations of travel of the respective carriers. In a similar fashion a second carrier or carriers dispensing thread traverse a path 74 from the lower right to the upper left of the pattern. Like the first path, the thread dispensed from carriers travelling this path alternately crosses over and under the other paths it encounters. A third path 76 travels around the intersection of the first path 72 and the second path 74. Like the first two paths, the thread dispensed from the carrier or carriers traversing path 76 alternately crosses over and under the threads of the other paths it encounters.

The lattice braid of FIG. 6a is seen to exhibit a generally square shape in cross-section with rounded corners. While the lattice braided suture has been found to provide less tensile strength than the spiral braided suture, the lattice braided suture can be strengthened by the inclusion of individual core threads running longitudinally through the interlocking lattice. A number of core threads may be located at the positions indicated at 82 in the lattice, at the positions indicated at 84, or both. This uniform distribution of core threads throughout the lattice, which results in secure capture of the individual threads within the loops of the lattice, has been found to provide a uniform distribution of tensile forces throughout the suture.

The outside of the lattice braided suture 70 is illustratively shown in FIG. 6b. The outer threads of the lattice are seen to be distributed in an angularly offset, generally parallel configuration. The drawing shows the generally parallel alignment of threads 72, 74, and 76 on the outside of the suture, forming a substantially smooth, longitudinally extending outer thread surface on each side of the square configuration. The rounded corners 78, shown on each side of the drawing, are also seen to smoothly extend along the length of the suture.

Apparatus for braiding the lattice braided suture of FIG. 6a is schematically shown in FIG. 7. The apparatus includes a plurality of rotating discs which transfer the carriers around and along their intended paths of travel. In a preferred embodiment there are three carriers traversing each path. Extending through the center of each rotating disc is a core thread 82, each of which becomes engaged in the lattice loops formed around its respective disc. The path 72 is traversed by carriers which rotate around disc 92a and are then transferred to the central disc 98. Each carrier travels halfway around disc 98 and is then transferred to disc 92b. The carriers travel around disc 92b and back to the central disc 98. After travelling around the other side of disc 98 each carrier is transferred back to rotating disc 92a and its starting point.

In a similar manner a second group of carriers on the path 74 travel around disc 94a and are transferred to the central disc 98. After travelling halfway around disc 98 each carrier is transferred to disc 94b. Each carrier travels around the rotating disc 94b, back to the other side of the central disc 98, and is returned to disc 94a and its starting point.

The third path 76 passes around rotating discs 96a, 96b, 96c, and 96d. The carriers which travel this path 76 pass around three-quarters of each disc before being transferred to the succeeding disc in the loop. As each carrier traverses the path 76 it is seen to pass inside the end discs of the other two paths 72 and 74, thereby enclosing the intersection of these two paths at the central disc 98.

The apparatus of FIG. 7 may be operated with a plurality of carriers travelling each path simultaneously. For instance, the apparatus may be operated with three carriers on each path to form a lattice braid of 9 threads. Alternatively each path may include 4 carriers for a total of 12 braided threads. As a third example, the apparatus may operate with 6 carriers on each path for a total of 18 threads in the braided suture.

Spiral braided sutures of the present invention can be expected to provide a 20% improvement in smoothness over conventionally braided sutures, a 20% improvement in pliability, and a 50% improvement in cylindrical uniformity. The improvement in smoothness is due to the parallel alignment of the suture threads on the outside of the spiral braided suture. The improvement is pliability is due to the thread crossovers of the spiral braid, which enhances fiber mobility; the individual threads in the spiral braided suture will easily move relative to each other as the suture is bent. And since there is no core to become misaligned or misshapen, cylindrical uniformity is improved.

Improvements in breaking strength can also be expected for the spiral braided suture. In a test of breaking strength remaining (BSR) after 21 days of in vivo use of an absorbable suture of conventional braid, typically 40-50% of the breaking strength remains. A 15-20% improvement in BSR can be expected in use of a spiral braided suture of the present invention under the same conditions.

The lattice braided suture provides the capability of producing a high quality composite suture, in which advantage is taken of the different characteristics of one

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000315

type of material for the braid and another type of material for the core threads. As discussed above, the lattice braided suture is substantially more immune to the problem of core pop than the conventionally braided suture, since the core threads are distributed throughout the structure of the braid and are not positioned in a single central location. Both the spiral and lattice braided sutures have been found to exhibit less surface area exposed to ambient conditions, and hence less exposure to moisture, than conventionally braided sutures.

What is claimed is:

1. A braided surgical suture in which a plurality of surgically compatible filaments are woven in a spiral braid by moving filament dispensers to different positions around a closed loop, wherein an individual dispenser in the loop is moved from its current position to a succeeding position which is at least two positions removed from said current position.

2. The braided surgical suture of claim 1, wherein the number of filaments is at least nine.

3. The braided surgical suture of claim 2, wherein said filament dispensers move around said loop in the same direction.

4. The braided surgical suture of claim 3, wherein said filament dispensers are organized in three uniformly distributed groups around said loop and the dispensers in each group move around said loop in unison.

5. The braided surgical suture of claim 3, wherein the number of filaments is twelve and wherein an individual dispenser in the loop is moved from its current position to a succeeding position which is three positions removed from said current position.

6. The braided surgical suture of claim 1, wherein the portions of said filaments which are visible on the outside of said braided suture are oriented substantially parallel to each other and are distributed in patterns which spiral around the outside of said suture.

7. The braided surgical suture of claim 1, wherein said surgically compatible filaments are woven in a spiral braid without any central, longitudinally extending core filaments.

8. A braided surgical suture in which a plurality of surgically compatible filaments are woven in a lattice braid by moving filament dispensers in three closed loop paths, a first and second of said paths being generally oblong and crossing over each other at a central intersection, and the third of said paths passing through the ends of said first and second paths outside said central intersection.

9. The braided surgical suture of claim 8, wherein said suture in cross-section exhibits a generally rectangular shape, with filaments traversing said ends of said first and second paths being located at the corners of said rectangular shape.

10. The braided surgical suture of claim 8, wherein each moving filament dispenser alternately passes over then under the filaments dispensed on the paths it intersects.

11. The braided surgical suture of claim 10, wherein there are at least three filament dispensers traversing each of said paths.

12. The braided surgical suture of claim 8, wherein there are formed a plurality of core fillament passageways located adjacent to the points of intersection of two or more of said paths.

13. The braided surgical suture of claim 12, further comprising at least four core filaments located in ones of said passageways.

14. The braided surgical suture of claim 13, wherein said core filaments are symmetrically distributed with respect to said point of intersection.

15. The braided surgical suture of claim 13, wherein said core filaments are made of a different surgically compatible material than that of said woven filaments.

16. The braided surgical suture of claim 12, further comprising at least nine core filaments located in ones of said passageways.

17. The braided surgical suture of claim 12, further comprising at least thirteen core filaments located in ones of said passageways.

* * * * *

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000316

United States Patent [19]
Silvestrini

[11] Patent Number: 4,979,956
[45] Date of Patent: Dec. 25, 1990

[54] DEVICE AND METHOD FOR TENDON AND LIGAMENT REPAIR

[75] Inventor: Thomas A. Silvestrini, East Lyme, Conn.

[73] Assignee: Pfizer Hospital Products Group, Inc., New York, N.Y.

[21] Appl. No.: 378,437

[22] Filed: Jul. 10, 1989

Related U.S. Application Data

[63] Continuation of Ser. No. 115,087, Oct. 30, 1987, abandoned.

[51] Int. Cl.[5] A61F 2/06
[52] U.S. Cl. 623/13
[58] Field of Search 623/11, 12, 16, 13, 623/18

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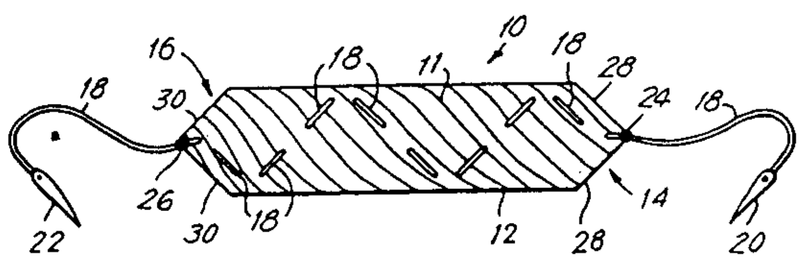
Primary Examiner—David J. Isabella
Attorney, Agent, or Firm—Peter C. Richardson; Lawrence C. Akers; John L. LaPierre

[57] **ABSTRACT**

A device, suitable for use in repairing a lacerated or severed tendon, particularly a hand flexor tendon, having a flat band body with opposite ends of the body designed to anchor connecting sutures. The device also finds applicability in the repair of lacerated or severed ligaments. Also disclosed is a method of repairing a severed tendon by implanting a flat band device suturing together the device and the tendon to effect an anastomosis along approximated ends of the severed tendon. Further disclosed is a method of repairing a lacerated or severed ligament.

28 Claims, 2 Drawing Sheets



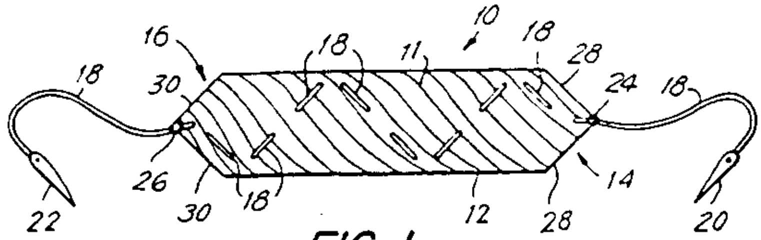


FIG. 1

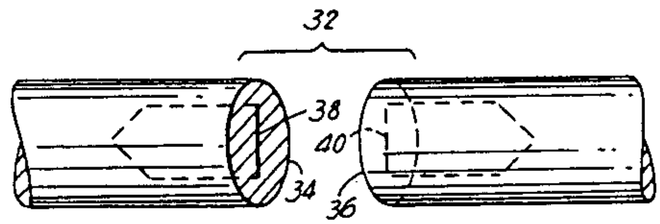


FIG. 2

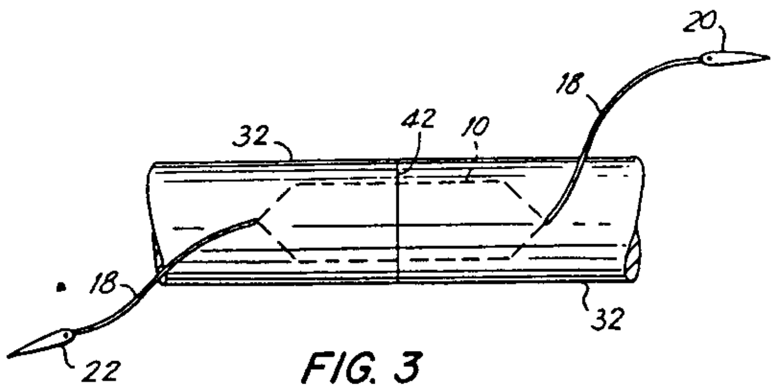


FIG. 3

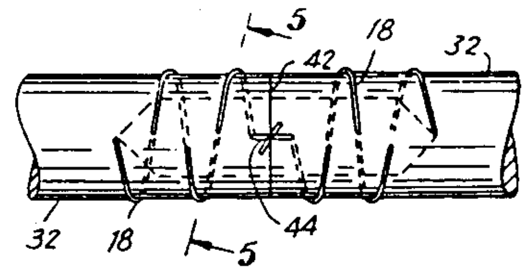


FIG. 4

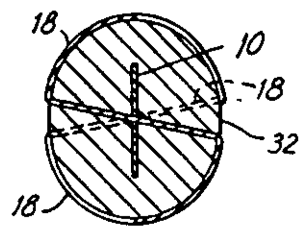


FIG. 5

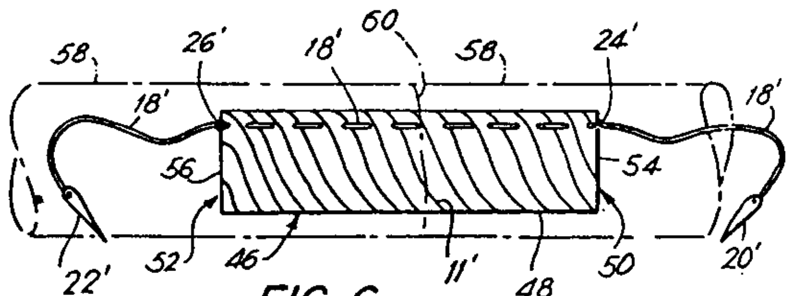


FIG. 6

DEVICE AND METHOD FOR TENDON AND LIGAMENT REPAIR

This is a continuation, of application Ser. No. 115,087, filed on Oct. 30, 1987, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a device for repairing severed or lacerated tendons and ligaments and, more particularly, the invention relates to a device having a flat band body constructed of resilient synthetic textile fiber and capable of receiving a suture element secured thereto at opposite ends of the body. Also contemplated by the invention are methods of anastomosing ends of severed or lacerated tendons and ligaments along an interface of approximated ends, by placing a device intratendonously, in the case of a tendon, or in juxtaposition, in the case of a ligament, bridging or spanning approximated ends, and suturing together either the tendon and the device or the ligament and the device. The objective is to provide a device and method for restoring tendons and ligaments, as nearly as possible, to their pre-damaged condition.

The successful repair of tendons, particularly hand flexor tendons, has been a problem for surgeons for many years. The past and current approach most commonly used by surgeons to achieve tendon repair is to anastomose severed tendons by using one of a variety of suturing techniques. A number of such techniques are commonly known and referred to as Bunnell, Kessler, Klienert, Tsuge and Becker, to name but a few. These techniques, while useful, are not entirely satisfactory because they allow surgeons to achieve successful repairs in only about 70% of the patients treated. Therefore, in view of the history of suture techniques which have been proposed and implemented from time to time by surgeons without any real improvement in repair strength or surgical result, the need for an improved device and method of anastomosis were clearly evident.

In addition to the foregoing suturing techniques most often used in tendon repair, in an effort to overcome the deficiencies encountered in the straight suturing approach, other devices and approaches have recently been tried to effect tendon repair. A typical device encountered might be one like that disclosed in U.S. Pat. No. 4,469,101. The teaching embodied in this patent specifies a structure having an open network or mesh of helically formed members to define a hollow tubular device wherein opposing ends of a lacerated tendon are introduced and brought into contact within the tube. The opposite ends of the tube are then sutured to the outer tendon wall and the contacting tendon ends are allowed to heal. Another device typically encountered in tendon repair might be one like that disclosed in U.S. Pat No. 4,501,029. This patent provides a continuous solid wall tubular device having in communication therewith a number of transversely extending passages. The tube is inserted between a replacement tendon and the tendon sheath. After blood supply from the sheath to the replacement tendon is established through the tubular passages, free movement of the tendon is established within the sheath. A third device encountered might be the plastic prosthetic tendon disclosed in U.S. Pat. No. 3,176,316. This patent provides a prosthesis having a solid central segment and hollow tubular ends comprising a mesh network wherein ends of a tendon are introduced and the prosthesis is sutured to the tendon.

There are certain disadvantages associated with each of the aforementioned tendon repair techniques and devices which the present inventive device and method either overcome or substantially lessen. Specifically, through the use of suturing techniques alone, irritations are minimized since sutures are buried inside the endotendon, but the strength of the anastomosis is not strong enough to allow aggressive mobility during healing. Consequently, there often occurs dehiscence of the suture leading to separation of approximated tendon ends, tissue ingrowth and slow or incomplete tendon healing. Inherent in the tubular mesh devices which are sutured to the tendon at ends of the devices is the exposure of a large amount of synthetic material on the outside of the epitenon which can cause excessive irritations. These irritations frequenty lead to adhesions between the injured tendon and the tendon surrounding which leads to retarded healing. The inventive device offers a minimum of irritation since it is substantially buried inside the endotendon, yet it offers higher strength of the anastomosed tendon compared to repairs using sutures. Lastly, the present device is one of structural simplicity which avoids both the complex geometry presented in the solid wall tubular device having a series of selectively positioned blood conveying passageways and the need to precisely locate such a prosthesis in the body to assure an adequate blood supply to the replacement tendon.

It should be understood that, while much of the foregoing discussion is directed toward tendon repair, the teachings encountered are also generally applicable to the repair of damaged ligaments. Clearly, there exists a need for a repair device which fosters superior mechanical repair properties and better healing characteristics than is currently found in the relevant surgical field. The present inventive device and method satisfies the need and, hence, advances the art field of tendon and ligament repair.

SUMMARY OF THE INVENTION

The present invention relates to a device used for repairing severed connective tissue of tendons and ligaments by approximating ends of the severed tissue and comprises an elongated body portion having a flat band structure with the body portion at opposite ends adapted to be connected to at least one needle bearing suture. The body structure may be a non-woven fabric, a composite reinforced with chopped fiber, a polymer sheet or a fabric which can be selected from a class of warp knits, weaves, nets and braids. The preferred braided fabric would be a triaxial braid or a flat band triaxial tube having either a monocomponent or bicomponent fiber element selected from a polymeric grouping and may include an elastomeric component. The preferred polymer for a monocomponent device body would be polyethylene terepthalate while for a bicomponent device the preferred polymers for the device body would be polyethylene terepthalate and polyester/polyether block copolymer. A suture or sutures may be lock stitched to opposite ends of the device body and may be incorporated into the body structure axially in either a longitudinal direction or in a bias direction. Additionally, a suture or sutures may be sewn into the body. The device body and associated suture or sutures may be covered with one or more gel coatings selected from a class of hydrogels with a preferred

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000320

coating being crosslinked calcium alginate. The body portion may assume a number of shapes but either a rectangle or a polygon, having ends tapered substantially to a point, is preferred. The ends of the body portion are preferably sealed to maintain edge integrity.

Also contemplated within the scope of the present invention are methods for repairing severed connective tissue of tendons and ligaments utilizing the inventive device heretofore described. Specifically, one method comprises the steps of creating a slot in the tissue of each opposing end of a severed tendon, where severance occured, inserting a first end of the device into one of the incised slots, inserting a second end of the device into the other of the incised slots, approximating opposing ends of the severed tissue, enclosing the device and therewithin bridging the ends, and suturing the tendon and the device together, passing sutures through the tendon and the implanted device along at least a portion of the length of the device, to anastomose the tendon along approximated ends of the severed connective tissue. A second method, relating to the repair of severed connective tissue of a ligament, comprises the steps of providing at least one inventive device, approximating opposing ends of the severed tissue, juxtaposing the ligament and the device with the device spanning approximated ends, and suturing the ligament and the device together, passing sutures through the ligament and the juxtaposed device along at least a portion of the length of the device, to anastomose the ligament along approximated ends of the severed connective tissue. In each of the methods, suturing will span at least the approximated ends and, preferably, suturing will be performed along substantially the entire length of the device.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific results obtained by its use, reference should be made to the corresponding drawings and descriptive matter in which there is illustrated and described typical embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an enlarged schematic representation of a tendon and ligament repair device, in accordance with the principles of the present invention, illustrating a flat band triaxial braid fabric structure having a single bias suture incorporated into the fabric body with the suture lock stitched to the body at opposite ends of the body.

FIG. 2 schematically illustrates a severed tendon, drawn at reduced scale, with slots incised in the tendon ends, before implantation of the repair device.

FIG. 3 is similar to FIG. 2, but with tendon ends approximated, and schematically illustrates the tendon repair device of FIG. 1 located within the endotendon prior to suturing.

FIG. 4 is similar to FIG. 3 and illustrates a completed repair showing suture penetration of both tendon and fabric body uniting tendon and device.

FIG. 5 is a cross-sectional view taken along line 5—5 of FIG. 4.

FIG. 6 is an enlarged schematic alternate embodiment of the invention showing in phantom a ligament with approximated ends and a flat band triaxial braid fabric structure, in place but prior to suturing, with a single axial suture incorporated into the fabric body with the suture lock stitched to the body at opposite ends thereof.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The description herein presented refers to the accompanying drawings in which like reference numerals refer to like parts throughout the several views, and in which, referring to FIG. 1, there is illustrated a repair device 10 of the present invention. The device has an elongated body portion 12 of flat band structural configuration, preferably a triaxial braid with the braid schematically designated as 11, and at a first end 14 and at a second end 16 a suture 18, having needles 20 and 22 at opposite ends, is connected or anchored to the body ends by a locking stitches 24 and 26. It should be understood that many types of knots or locking stitches, such as a double throw suture locking stitch, would be suitable to anchor the suture to the body portion. Locking the suture to the body could be accomplished at any time, as desired. The device shown in FIG. 1, it should be remembered, is a schematic representation and, therein depicted, the device has a flat band triaxial braid fabric structure with a single bias suture braided into the fabric body. It should also be understood that more than one suture could be attached to or incorporated into the fabric body and locked to the body ends. Furthermore, a suture or sutures could be sewn or stitched to the body along the body length instead of being braided into the body. In the preferred form of the device, the lock stitching of the suture to the ends of the braid body prevents the braid structure from bunching during insertion into tissue. The stitching also serves to center the suture pull of the device, thereby easing the insertion of the device into connective tissue. Also contemplated within the scope of the invention is a suture or sutures not incorporated into the fabric body per se but merely locked to one or both of the body ends. The ends 14 and 16 may be sealed along edges 28 and 30 to maintain edge integrity. Edge sealing may be accomplished using an ultrasonic sealing process or other means of heat treatment to keep edges from unraveling or separating.

The device body portion may be structurally configured as a non-woven fabric, a polymer reinforced with chopped fiber, a polymer sheet, a warp knit, a weave, a net or a braid. The construction of the desired flat band fabric into any one of these body portion structural configurations would be within the skill of those who manufacture textile products. A preferred structure would be a braid, preferably a triaxial braid. A flat band or flattened triaxial tube is within the scope of the invention. A triaxially-braided fabric, such as the ones schematically depicted in FIG. 1 and FIG. 6, and the methods of manufacturing them in different configurations, namely, flat bands, flat tubes, tubes, patches and strips, to name but a few, are well known to those skilled in the art of manufacturing braided polymeric articles. The triaxial braid may consist of a monocomponent fiber selected from a group of polymers consisting of polyethylene terepthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetheretherketone, polyester/polyether block copolymer, liquid crystal polymeric fiber, nylon and carbon. The preferred polymer would be polyethylene terepthalate. The triaxial braid may also have a bicomponent fiber makeup with its components selected from the same polymer grouping. One of the components of the bicomponent

braid should be elastomeric with the preferred elastomer being polyester/polyether block copolymer. The preferred bicomponent braid comprises a first component of polyethylene terepthalate and a second component of polyester/polyether block copolymer.

The device may be coated to improve the ease of surgical installation and to minimize irritation to tissue during healing. The suture or sutures could also be coated to minimize adhesions formed during healing. The coating could be a gel, specifically a hydrogel, selected from the group consisting of sodium alginate, hyaluronic acid, crosslinked hyaluronic acid, crosslinked calcium alginate and a calcium alginate crosslinked hyaluronic acid mixture. The preferred lubricious coating for the device and sutures is crosslinked calcium alginate.

The device body as shown in FIG. 1 defines a polygon having opposed longitudinal ends each tapering to a point with the points, preferably, lying along the central longitudinal axis. The body may, however, as is shown in FIG. 6, take a rectangular shape. Other flat band structural shapes would be suitable and are within the scope of the present invention.

Turning to FIG. 2 through FIG. 5, in FIG. 2 there is shown severed connective tissue of a tendon 32 having separated ends 34 and 36. In each end 34 and 36, slots 38 and 40 have been incised within the endotendon using a suitable blade or cutting device (not shown). Each slot 38 and 40 will preferably be configured to conform substantially to one half the size of the repair device 10. FIG. 3 shows device 10 located within slots 38 and 40, suture 18 at opposite ends 14 and 16 of device 10 passing through tendon 32, and separated tissue ends 34 and 36 approximated as shown at 42. Device 10 is closed within the approximated tissue, bridging ends 34 and 36 which are in contact along joint 42. FIG. 4 and FIG. 5 depict a completed repair wherein the tendon and the device have been sutured together and the suture ends tied at 44. Suturing of the device into the tendon can be accomplished in many different ways. Thus, the device does not restrict the personal suturing preference of different surgeons. Anastomosis of the tendon will occur along approximated ends at 42. Suturing should span at least the approximated ends and, preferably suturing should be performed along substantially the entire length of the implanted device 10.

Turning to FIG. 6, there is schematically shown an alternate embodiment of the invention. Here depicted is a rectangular flat band repair device 46 having a triaxially braided fabric structure 11' and a suture 18', bearing needles 20' and 22', incorporated into elongated body portion 48 and axially oriented in a longitudinal direction. At first and second ends 50 and 52, suture 18' is affixed to the body ends by locking stitches 24' and 26'. As aforementioned in respect to the device 10, many types of knots or locking stitches would be suitable to affix the suture to the body portion and stitching could be accomplished when desired, namely, at time of manufacture or by a surgeon prior to device use. Lock stitching would be particularly useful, in addition to ease in installation, that is, prevention of fabric bunching, to keep the suture from being pulled through the fabric. More than one suture could be used and attached to or incorporated into the body fabric. Additionally, a suture might be sewn to the body along the length of the body rather than being braided into the body. The ends 50 and 52 may be sealed along edges 54 and 56 to maintain edge integrity, as in the case of device 10. All of the other structural features associated with device 10 are equally suitable for device 46.

In FIG. 6, device 46 is shown to be particularly useful in the repair of severed connective tissue of a ligament, illustrated in phantom and designated as 58. It should be understood, however, that a device of rectangular configuration would be equally useful in tendon repair and slots 38 and 40, as shown in FIG. 2, could assume a rectangular shape. Likewise, device 10 would be equally suitable in the repair of a ligament. Device 46, as provided in FIG. 6, is shown positioned alongside ligament 58 having severed ends approximated at 60. The device spans the approximated ends. It should be understood that more than one device could be used for the repair. While a completed repair is not shown in FIG. 6, a suturing technique like that shown in FIG. 4, and other techniques described in respect thereto, could be used to suture together ligament 58 and device 46. Anastomosis of the ligament will occur along approximated tissue ends at 60. Suturing should span at least the approximated ends and, preferably, suturing should be performed along substantially the entire length of device 46. In each of the repair techniques, namely, tendon and ligament, devices 10 and 46 are biocompatible and can be made from permanent, non-body absorbable materials, or from resorbable materials.

As heretofore mentioned, braiding can be accomplished using known technology and the inventive device can be manufactured using existing braiding machines modified to incorporate longitudinal fibers into the braided structures. By way of example, and not to be construed as limiting the invention, a 0.07 inch wide monocomponent polyethylene terepthalate device 10 can be braided on a 32-carrier triaxial braider using 70 denier white polyethylene terepthalate type 52 multifilament yarns and a single green 4-0 polyethylene terepthalate suture. The finished product is composed of 31 polyethylene terepthalate yarns and one 4-0 polyethylene terepthalate suture on the bias and 16 polyethylene terepthalate yarns on the longitudinal axis. In another example, a 0.07 inch wide bicomponent device 10 can be braided on a 24-carrier triaxial braider using 220 denier polyester/polyether block copolymer monofilaments, 70 denier white polyethylene terepthalate type 52 multifilament yarns, and a single green 4-0 polyethylene terepthalate suture. The finished construction is composed of 23 polyethylene terepthalate yarns and one 4-0 polyethylene terepthalate suture on the bias, and 12 polyester/polyether block copolymer fibers on the longitudinal axis. It should be understood that wider or narrower devices could be manufactured. The device is made from safe materials that surgeons are comfortable implanting and the device can easily be made in a variety of sizes to address different soft tissue repair situations. Device needles could be swaged onto the suture ends of affixed by other suitable means. Laboratory testing of a repair device used to anastomose explanted canine and bovine tendon has demonstrated that the initial strength of the repair junction is approximately twice the strength of tendon repairs made using conventional suturing techniques.

While in accordance with provisions of the statutes there is described herein specific embodiments of the invention, those skilled in the art will understand that changes may be made in the form of the invention covered by the claims appended hereto without departing from the scope and spirit thereof, and that certain features of the invention may sometimes be used to an

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000322

advantage without corresponding use of the other features.

I claim:

1. A device for use in repairing severed connective tissue of tendons and ligaments by approximating severed ends of said tissue bringing said tissue ends into abutment comprising an elongated body having a flat band structure, said body being sized and configured for enclosure within said abutting tissue ends, and with said body at first and second opposed non-bifurcated ends adapted to be connected to at least one needle bearing suture, with said suture being incorporated into said body substantially the length thereof, said suture being oriented in a bias direction.

2. The device according to claim 1 wherein said structure is a non-woven fabric.

3. The device according to claim 1 wherein said structure is a polymer reinforced with chopped fiber.

4. The device according to claim 1 wherein said structure is a polymer sheet.

5. The device according to claim 1 wherein said structure is a fabric selected from the group consisting of warp knits, weaves, nets and braids.

6. The device according to claim 5 wherein said fabric is a braid.

7. The device according to claim 6 wherein said braid is a triaxial braid.

8. The device according to claim 7, wherein said braid comprises a monocomponent fiber forming element.

9. The device according to claim 8 wherein said element is a polymer selected from the group consisting of polyethylene terepthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetherether ketone, polyester/polyether block copolymer, liquid crystal polymeric fibers, nylon and carbon.

10. The device according to claim 9 wherein said polymer is preferably polyethylene terepthalate.

11. The device according to claim 7 wherein said braid comprises a bicomponent fiber forming element.

12. The device according to claim 11 wherein said element is a plurality of polymers selected from the group consisting of polyethylene terepthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetherether ketone, polyester/polyether block copolymer, liquid crystal polymeric fibers, nylon and carbon.

13. The device according to claim 12 wherein at least one of said polymers is elastomeric.

14. The device according to claim 13 wherein said elastomeric polymer is preferably polyester/polyether block copolymer.

15. The device according to claim 12 wherein said polymers are preferably polyethylene terepthalate and polyester/polyether block copolymer.

16. The device according to claim 1 wherein said suture is lock stitched to said ends.

17. The device according to claim 1 wherein said suture is sewn into said body.

18. The device according to claim 17 wherein said suture is axially oriented in a longitudinal direction.

19. The device according to claim 1 wherein said body is covered with a gel coating.

20. The device according to claim 19 wherein said body and said suture are covered with a gel coating.

21. The device according to claim 20 wherein said coating is a hydrogel selected from the group consisting of sodium alginate, hyaluronic acid, crosslinked hyaluronic acid, crosslinked calcium alginate and a calcium alginate crosslinked hyaluronic acid mixture.

22. The device according to claim 21 wherein said hydrogel is preferably crosslinked calcium alginate.

23. The device according to claim 1 wherein said body defines a polygon.

24. The device according to claim 23 wherein said polygon is a rectangle.

25. The device according to claim 23 wherein at least one of said ends of said body terminates substantially in a point.

26. The device according to claim 25 wherein said point lies along a central axis of said body.

27. The device according to claim 1 wherein said ends are sealed proximate end edges to maintain edge integrity.

28. The device according to claim 1 wherein said body is a flat band triaxial tube.

* * * * *

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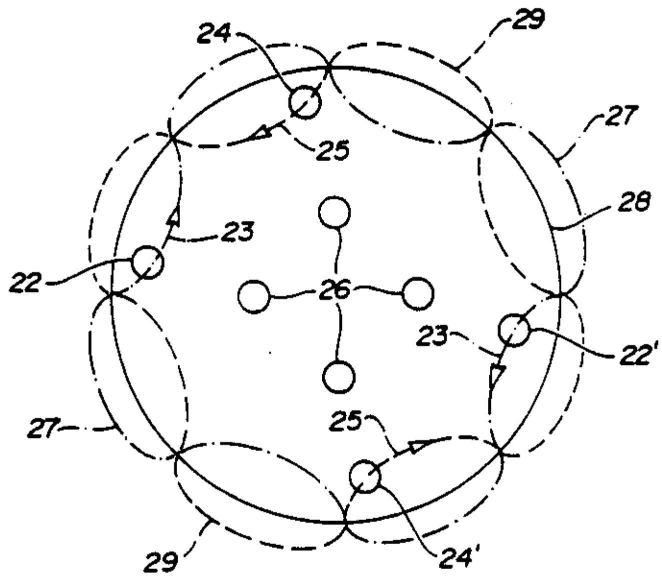
FIG-1



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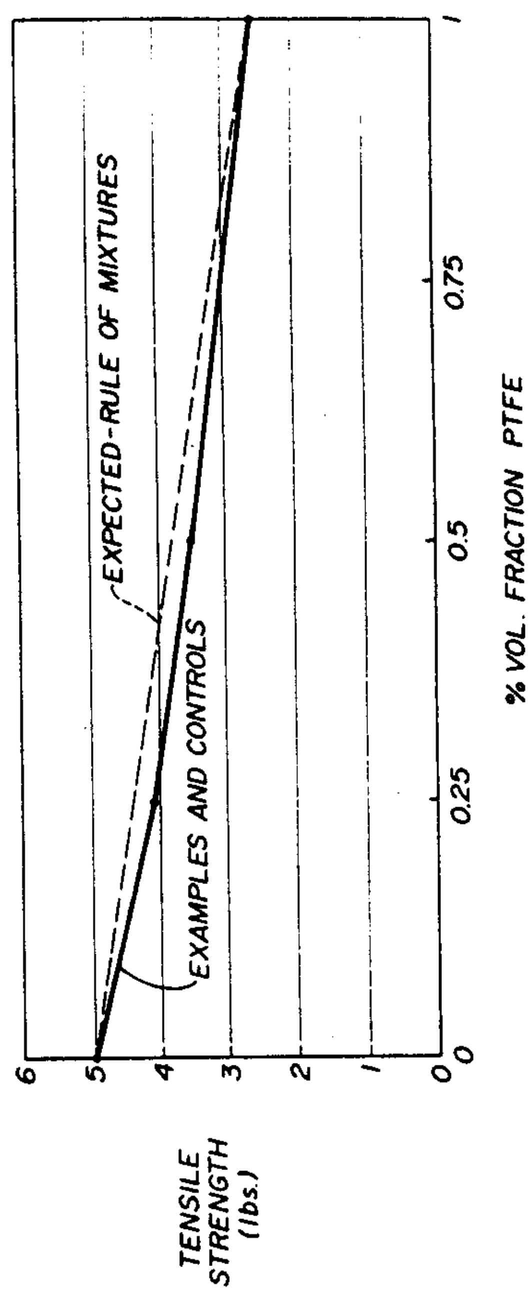
[redacted]

FIG-2



As Originally Filed

838511

[redacted]

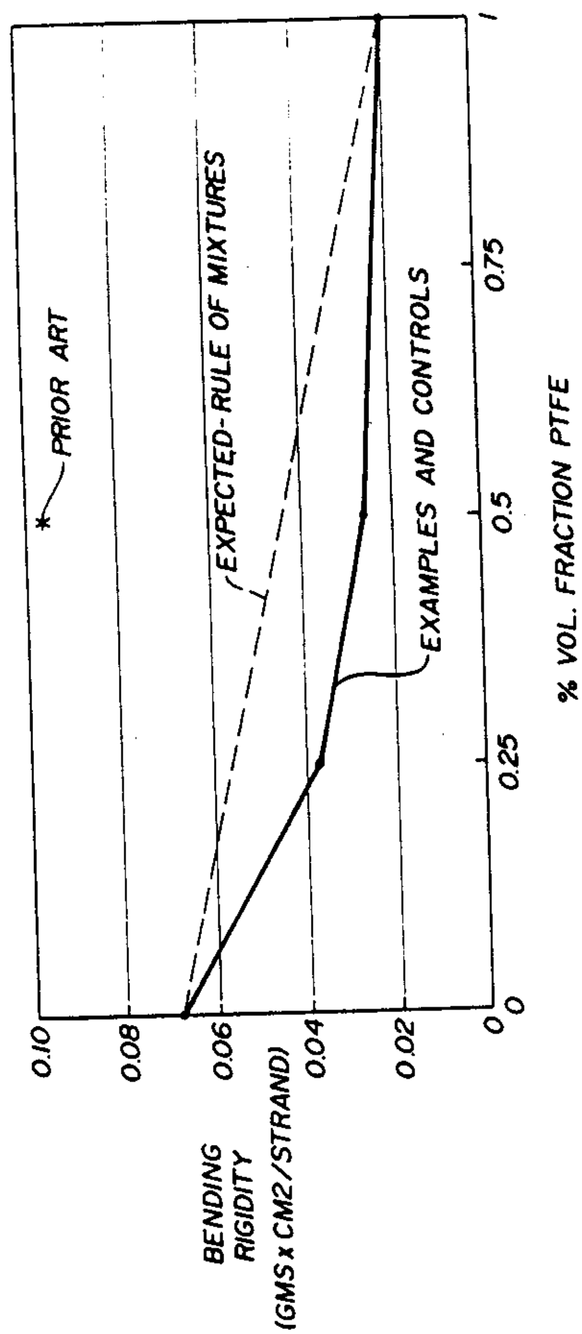


FIG-3

d 11 16

11. 4,959,069, Sep. 25, 1990, Braided surgical sutures; Karl W. Brennan, et al., 606/228; 87/7; 428/224 [IMAGE AVAILABLE]

16. 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures ; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

=) d his

(FILE 'USPAT' ENTERED AT 12:54:30 ON 25 JUN 92)

L1	5156	S SUTURE#
L2	8197	S BRAID?
L3	361	S L1 AND L2
L4	2442	S INTERTWIN?
L5	18	S L3 AND L4
L6	103608	S COMPOSITE
L7	(1043648)	S S
L8	3	S L5 AND L6
L9	20	S L6(3A)L1

=) d 13 37 57 188

37. 5,059,213, Oct. 22, 1991, Spiroid braided suture ; Michael P. Chesterfield, et al., 606/228 [IMAGE AVAILABLE]

57. 5,019,093, May 28, 1991, Braided suture ; Donald S. Kaplan, et al., 606/228, 230 [IMAGE AVAILABLE]

188. 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures ; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

=)

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    d his

      (FILE 'USPAT' ENTERED AT 08:07:48 ON 22 OCT 92)
L1          6291 S SUTURE# OR LIGATURE#
L2          8447 S BRAID?
L3           230 S L1(5A)L2
L4        117600 S COMPOSITE OR HETEROGENEOUS
L5            40 S L4 AND L3
L6          9257 S PET OR POLYETHYLENETEREPHTHALATE
L7         49419 S PTFE OR TEFLON OR POLYTETRAFLUOROETHYLENE OR FLUOROPOLYM
ER
L8           735 S L6 AND L7
L9             5 S L8 AND L5
L10           35 S L5 NOT L9
L11            1 S L10 AND L6
L12            6 S L10 AND L7
L13           13 S L2 AND L4 AND L6 AND L7

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d 19 1 2 3 4 5

1. 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230 —

2. 4,461,298, Jul. 24, 1984, Composite sutures of silk and hydrophobic thermoplastic elastomers; Shalaby W. Shalaby, et al., 606/231; 528/296 528

3. 4,441,496, Apr. 10, 1984, Copolymers of p-dioxanone and 2,5-morpholinediones and surgical devices formed therefrom having accelerated absorption characteristics; Shalaby W. Shalaby, et al., 606/230; 528/354; 606/231 ~~528~~ 606

4. 4,137,921, Feb. 6, 1979, Addition copolymers of lactide and glycolide and method of preparation; Yuzi Okuzumi, et al., 606/230; 525/411, 420; 528/354; 606/231; 623/1 606 ~~528~~

5. 4,052,988, Oct. 11, 1977, Synthetic absorbable surgical devices of poly-dioxanone; Namassivaya Doddi, et al., 606/231; 528/354; 623/66 528

=> d 1 2 4 8 13

1. 5,147,400, Sep. 15, 1992, Connective tissue prosthesis; Donald S. Kaplan, et al., 623/13, 1, 11, 66 [IMAGE AVAILABLE] 623

2. 5,116,360, May 26, 1992, Mesh composite graft; Leonard Pinchuk, et al., 623/1, 11, 12 [IMAGE AVAILABLE] 623

4. 4,990,158, Feb. 5, 1991, Synthetic semiabsorbable tubular prosthesis; Donald S. Kaplan, et al., 623/1; 57/225 [IMAGE AVAILABLE] 623

8. 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230 —

13. 3,748,828, Jul. 31, 1973, PROCESS AND APPARATUS FOR FLUID-LIQUID CONTACTING; Simon Lefebvre, 55/2, 29, 70, 73, 90, 93, 122, 233, 240, 300, 481, 527; 261/95, 103 55

=>

623 4-4C04

57 4-5D10

606 4-4C04

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000329

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 16, 1991

Application or Docket Number: 838511

CLAIMS AS FILED - PART I

FOR	NUMBER FILED (Column 1)		NUMBER EXTRA (Column 2)	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE					$ 345.00	OR		$ 690.00
TOTAL CLAIMS	24	minus 20 =	* 4	x $10=		OR	x $20 =	80
INDEPENDENT CLAIMS	1	minus 3 =	* 0	x 36 =		OR	x 72 =	
MULTIPLE DEPENDENT CLAIM PRESENT				+ 110 =		OR	+ 220 =	
				TOTAL		OR	TOTAL	770

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

AMENDMENT A

	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
Total	* 24	Minus	** 29	=	x $10=		OR	x $20 =	
Independent	* 2	Minus	*** 3	=	x 36 =		OR	x 72 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+ 110 =		OR	+ 220 =	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
Total	*	Minus	**	=	x $10 =		OR	x $20 =	
Independent	*	Minus	***	=	x 36 =		OR	x 72 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+ 110 =		OR	+ 220 =	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
Total	*	Minus	**	=	x $10 =		OR	x $20 =	-
Independent	*	Minus	***	=	x 36 =		OR	x 72 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+ 110 =		OR	+ 220 =	
					TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Form PTO-875
(Rev. 12-91)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000330

STAPLE AREA

PATENT NUMBER

APPLICATION SERIAL NUMBER
07/838,511

APPLICANT'S NAME (PLEASE PRINT)
Hunter et al.

IF REISSUE, ORIGINAL PATENT NUMBER
—

ORIGINAL CLASSIFICATION

CLASS	SUBCLASS
606	231

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)			
606	228			
87	7	9		
428	[illegible]	370		

INTERNATIONAL CLASSIFICATION

D	O	H	C		1/00

GROUP ART UNIT
1504

ASSISTANT EXAMINER (PLEASE STAMP OR PRINT FULL NAME)
CHRISTOPHER W. RAIMUND

PRIMARY EXAMINER (PLEASE STAMP OR PRINT FULL NAME)
GEORGE F. LESMES

PTO 270
(REV. 5-91)

ISSUE CLASSIFICATION SLIP

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

PTO 1130 (REV 1/89)

U.S. DEPARTMENT OF COMMERCE– PATENT & TRADEMARK OFFICE

PACE DATA ENTRY CODING SHEET

1ST EXAMINER	ESTEY	DATE	3-4-92
2ND EXAMINER		DATE	

APPLICATION NUMBER	TYPE APPL	FILING DATE MONTH	DAY	YEAR	SPECIAL HANDLING	GROUP ART UNIT	CLASS	SHEETS OF DRAWING
07 838511	1	02	19	92		1304	264	3

TOTAL CLAIMS	INDEPENDENT CLAIMS	SMALL ENTITY?	FILING FEE	FOREIGN LICENSE	ATTORNEY DOCKET NUMBER
24	1	0	770	Y	ETH-782

CONTINUITY DATA

CONTINUITY CODE	STATUS CODE	PARENT APPPLICATION SERIAL NUMBER	PARENT PATENT NUMBER	PARENT FILING DATE MONTH	DAY	YEAR
		0				
		0				
		0				
		0				
		0				

PCT/FOREIGN APPLICATION DATA

FOREIGN PRIORITY CLAIMED	COUNTRY CODE	PCT/FOREIGN APPLICATION SERIAL NUMBER	FOREIGN FILING DATE MONTH	DAY	YEAR

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000332

[redacted]

SEARCHED

Class	Sub.	Date	Exmr.
606	228	6/25/92	CWR
606	230	6/25/92	CWR
606	231	6/25/92	CWR
606	update 228 230 231	8/26/92	CWR
606 87 428	228 231 7 8 9 225	11/9/93	CWR

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
606	231	11/15/93	CWR

SEARCH NOTES

	Date	Exmr.
APS SEARCH	6/25/92	CWR
APS SEARCH	10/22/92	CWR

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		INIT	DATE
POSITION		78	3/3/92
CLASSIFIER		319	3-4-92
EXAMINER		291	3-5-92
VERIFIER			
TYPIST			
CORPS CORR.			
SPEC. HAND.			
FILE MAINT.			

INDEX OF CLAIMS

SYMBOLS

✓	Rejected
=	Allowed
– (Through numeral)	Canceled
÷	Restricted
N	Non-elected
I	Interference
A	Appeal
O	Objected

Claim Final	Claim Original	Date 7/28/92	Date 11/2/92	Date 2/12/93	Date 8/12/93					
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—	2	+			+					
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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000334

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APPROVED FOR LICENSE

INITIALS MAR 0 3 92 4 6

RECEIVED
Received or Mailed MAR 0 9 1992
GROUP 150

Entered or Counted

CONTENTS

1. Application papers. 2/19/92
2. Prior Art
3. Rej. 3 mo.
4. Request for Recon
5. Rej. 3 mo.
6. Request for Recon
7. Rej. 3 mo. 8/9/93
8. 8/9/93
9. 8/9/93
10. 8/9/93
11. 11/18/93
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14. 5/27/94
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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000335

HERMES DECLARATION
EXHIBIT 16

An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture

Bruce E. Cohan, MD; Jan W. Leenslag, MsC; Jon Miles; Albert J. Pennings, PhD

• An ultrastrong polyethylene fiber was evaluated as an ophthalmic suture. Properties of this fiber and of nylon, polypropylene, and polyester sutures were measured by standard techniques for fiber testing and for testing knot characteristics of sutures. Their behavior in cataract and keratoplasty surgery was assessed qualitatively. The ultrastrong polyethylene fiber has great tensile strength, high flexibility, and is very inelastic. Its strength and knot security provide safe incision closure and it has good biocompatibility. Ultrastrong polyethylene fiber is potentially superior to nylon, polypropylene, and polyester in the most important characteristics of a nonabsorbable monofilament polymer ophthalmic microsuture.

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In the 1960s, when the surgical microscope dramatically transformed surgery of the anterior segment of the eye, the most advanced suture material was the 40-μm (8-0) twisted multifilament virgin silk of Barraquer. Silk has excellent handling and knotting characteristics because it is very flexible and inelastic, and it has a highly textured surface. Surgeons using it as a microsuture were dissatisfied with it, however, because they believed that its strength was not adequate and they considered it too large for microsurgery. Also, since silk is of biologic origin, it causes significant tissue reaction; this and its biodegradability further limit its effectiveness in maintaining security of incision closure.

Microscopic eye surgery required a better suture material. In the early 1960s, the synthetic polymer, nylon, led to a further transformation in eye surgery. Undyed 40-μm nylon monofilaments were first used in eye surgery at the University of Tubingen in Germany.[1] Subsequently, 25-μm black-dyed nylon was provided by manufacturers, and for most eye surgeons it soon replaced silk because it was so much finer, stronger, and more inert. Although handling and knotting nylon sutures is more difficult because they are less flexible, more elastic, and smoother than silk, surgeons soon adapted to these characteristics. Two polymer monofilament sutures for eye microsurgery subsequently appeared that are comparable to nylon in their strength, flexibility, elasticity, and biocompatibility—polypropylene in the 1970s and polyester in 1983—but nylon continues today to be by far the most commonly used suture for anterior segment surgery.

Sutures of a fourth polymer, polyethylene, have also been available, but they have not been used for eye surgery. Histologic studies of polyethylene sutures have shown that they produce minimal tissue reaction, comparable to that of nylon, polypropylene, and polyester.[2,3] Polyethylene is widely used in orthopedic surgery as a replacement material for artificial hip-joint and knee components because of its excellent mechanical properties, biocompatibility, and biostability.[4-7]

Recently, ultrastrong polyethylene fibers have been produced with new methods of polymer processing.[8] These fibers have a tensile strength of up to 4.7 times greater than that of comparable steel wire, and they are also very inelastic and very flexible.

In this study, we evaluated ultrastrong polyethylene fibers in comparison with nylon, polypropylene, and polyester ophthalmic sutures by (1) measurement of mechanical properties with standard fiber-testing techniques, and (2) qualitative assessment of their behavior as sutures during their use in cataract and keratoplasty surgery, and of the appearance on postoperative examinations of the tissue response and of the fiber itself.

MATERIALS AND METHODS

The ultrastrong polyethylene fibers used in this study were made from an ultrahigh-molecular weight source material, Hi-Fax 1900 linear polyethylene, having a weight-average molecular weight of about 4×10^6 kg/kmole. The fibers were produced by hot-drawing of filaments obtained by a process of crystallization from flowing solutions of the polymer ("surface growth" technique). Details of these processes are described elsewhere.[8-10]

The polyethylene fibers are monofilaments with a ribbon shape. The nylon, polypropylene, and polyester ophthalmic sutures evaluated are round monofilaments; they were taken from commercially purchased packages of 10-0 sutures for

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From the Eye Research Fund Laboratory, University of Michigan, Ann Arbor (Dr Cohan and Mr Miles), and the Laboratory of Polymer Chemistry, University of Groningen, the Netherlands (Dr Pennings and Mr Leenslag).

Reprint requests to the Eye Research Fund Laboratory, University of Michigan, 2350 Washtenaw Ave, Ann Arbor, MI 48104 (Dr Cohan).

operating room use of black Ethilon, blue Prolene, and green Mersilene, respectively (Ethicon Inc).

Mechanical Testing

Suture sizes are given designations based on their diameters, on the assumption they are round; those with a diameter of from 20 to 29 μm are designated as 10-0 according to the *US Pharmacopoeia*.[19] The cross-sectional area of each of the four fibers has to be taken into account in comparing the results of mechanical properties testing. The cross-sectional area was determined under exclusion of pores by dividing the mass per unit length by the density of the material, assuming for polyethylene, 1,000 kg/cu m; for nylon 6/6, 1,130 kg/cu m; for isotactic polypropylene, 900 kg/cu m; and for polyester (polyethylene terephthalate), 1,457 kg/cu m. To show the shape and structure of the polyethylene fibers, specimens were gold coated and then examined in a scanning electron microscope, operated at 20 to 40 kV.

The standard method for determining the mechanical properties of a suture is by measuring its response to an applied load according to the procedure specified by the *US Pharmacopoeia*.[19] Each end of the fiber is held by a clamp in a tensile strength testing machine. One clamp is connected to a motor-driven screw that loads the fiber by separating the clamps at a constant speed, and the other clamp is attached to a force gauge. The response of a fiber (at each point during the loading) is expressed as *stress*, which is the measured force divided by the cross-sectional area, and *strain*, which is the measured elongation. The appropriate unit of stress for monofilaments[21] is the gigapascal (GPa), which is equivalent to 1,000 newton/sq mm; strain is reported as percentage increase in length of the specimen. The result of this testing is a "stress-strain curve" and the tensile strength of a fiber is the stress at the end of the curve, the point at which the fiber breaks. From the stress-strain curve of a material is derived the modulus of elasticity (Young's modulus, E), a constant in the equation relating stress to strain.

The mechanical properties of the fibers in this study were measured dry and at room temperature using a tensile strength tester with pneumatic clamps (Instron, models 1195 and 2712-002). The distance between the clamps and the clamp separation speed was 10 to 12 mm/min. The values presented are the average of five tests; measurement error is about 0.02 GPa. The configuration of knots tested in this study is described by a code[14] in which the number of turns for each throw is indicated in numerals and the manner of joining the throws is shown by = for in parallel (square) and X for crosswise (granny).

The basic stress-strain curves for fibers of each of the four materials tested were obtained with a continuous, unknotted specimen loaded in the axial direction of the fiber; *tensile strength* is the end point, the point at which the fiber breaks.

A second series of stress-strain curves was obtained by loading the ends of a single, continuous fiber that is tied with a surgical knot (2 = 1) around flexible rubber tubing of 6.5-mm inside diameter and 1.6-mm wall thickness.[14] These curves show the weakening effect of a knot on each fiber; the *knot pull strength* is the end point, the point at which fibers knotted in this way break.[14,17]

A third series of stress-strain curves was obtained by loading a specimen of two segments of a fiber joined by a knot. It is prepared from a single continuous fiber by first tying a knot of the configuration to be tested around a tube and then cutting the loop thus formed, yielding a specimen of two strands joined by the knot. These stress-strain curves give an indication of the security of that particular knot configuration with that fiber; *knot holding strength* is the end point, the point at which the knot breaks or slippage through the knot is observed.

Although there are no standard methods to describe quantitatively the important property of suture flexibility, it is related to torsional stiffness which can therefore be used as an approximate measure of flexibility.[18] Fibers of the four materials equal in length (0.245 m) were held vertically and loaded with a weight (0.5×10^{-3} kg) attached at one end. The upper end of the fiber was rotated until the weight also started to rotate. The number of turns a fiber takes before the weight starts to rotate constitutes a relative measure of its flexibility. Because silk has always been highly valued for its excellent flexibility, it was also tested in this way. Because the finest-diameter silk suture commercially available is 9-0 black twisted virgin silk (Ethicon), specimens of it were compared with polyethylene fiber of about the same cross-sectional area.

Clinical Evaluation

The performance of the ultrastrong polyethylene fiber as an ophthalmic suture was evaluated qualitatively by observing its behavior during surgery. Its biocompatibility and functional adequacy after surgery were assessed, also in a qualitative way, on postoperative examinations. These observations were compared with prior experience in cataract surgery with the nylon in several thousand operations and the polypropylene in several hundred operations, and with subsequent experience with the polyester in several hundred operations. The comparisons in the keratoplasties were with several dozen in which the nylon was used.

Between February 1982 and April 1984, the polyethylene fiber was used to close 237 corneoscleral cataract incisions and, in nine patients, for penetrating keratoplasty. In the cataract operations it has also been used for suturing iris and conjunctiva. Lengths of the undyed ribbon-shaped polyethylene fiber having a width of 37 μm and a thickness of 15 to 25 μm were threaded and tied to an eyed "flat-lancet point" needle; this needle has a wire size of 150 μm, a 4-mm chord length, and a ⅜ curve; its eye is 60 × 250 μm. For corneoscleral incision closure, after placing a central apposition suture, a continuous chain[7] (running interlocking[8]) suture was used. A single continuous running suture was used in the keratoplasties. All knots were of the 3 = 2 = 1 "reinforced" configuration.[7]

During Surgery.—The response of the polyethylene fiber to the three basic suture-related surgical maneuvers (placement, tightening, and knot tying) was assessed during surgery on the basis of the usual visual and kinesthetic observations. Among the mechanical properties evaluated that affect a suture's handling characteristics are tensile strength, shear strength, compressive strength, elasticity, flexibility, and surface friction. Tensile, shear, and compressive strength affect a suture's behavior during pulling, bending, and grasping, respectively; elasticity, flexibility, and friction are factors in suture response to stretching, bending, and tissue drag, respectively.

During suture placement, as it is pulled through the needle track, the suture is subject primarily to tensile stress, acting along the direction of pull. Shear stress occurs near the point of attachment of suture to needle, whether it is swaged or threaded through an eyed needle. Resistance to pull-through affects the amount of tensile and shear stress in the suture. Surface friction and flexibility of a suture material are factors in the pull-through resistance of the suture as it enters, follows, and exits the suture canal.[21]

During suture tightening, in addition to visual cues of tissue stress, proper apposition pressure is achieved by sensing the reaction force in the suture. Elasticity contributes to the suture tension, and this affects the kinesthetic estimation of incision closure pressure. In addition to tensile and shear stress in the suture, during tightening there is also the compressive stress from the forceps grasp.

The behavior of the fiber during knot tying was also observed and is also determined by several mechanical properties. Tensile, shear, and compressive strengths are necessary to maintain the integrity of the knot as it is tied. Flexibility and surface friction determine the amount of force required for knot tying and also the tendency of the knot to slip and become too tight.

Postoperatively.—The tissue response to the polyethylene suture and the appearance of the suture itself were assessed on routine postoperative evaluations beginning on the first day after surgery. Irritative symptoms were evaluated and then slit-lamp examination was performed.

In the cataract cases, the early postoperative reaction is obviously due primarily to the conjunctival dissection and the presence of the conjunctival suture, and the conjunctival flap often limits the visibility of the corneoscleral suture. With removal of the conjunctival suture, the conjunctival reaction subsides in a relatively predictable way unless the response to the corneoscleral suture prolongs it. As visualization of the corneo-scleral suture improves, any possible isolated response of the

through the eye of the needle. In only two instances did it break at this point of extreme bending despite the multiple passes through the tissue. Sutures of the other three polymers used with an eyed needle characteristically resist this bending for only a few passes before breaking. While using the polyethylene fiber, full confidence developed that the possibility of fiber break was not a factor during surgery. When this series was completed and subsequent surgery was performed using the other polymer sutures, the amount of stress that they could sustain without break had to be "relearned."

An important property of the polyethylene fiber which is apparent during surgery is that it is very inelastic. This makes proper tension on the fiber easier to obtain during tightening a continuous suture and the first throw of a knot because of the negligible contribution of fiber stretch to the kinesthetic estimation of apposition pressure. The polyethylene fiber conducts mechanical tension so well that one obtains a direct sense of the tissue stress during tightening and tying.

Another attribute of the polyethylene fiber observed during its use as a suture is its flexibility. It tends to behave much like silk and without the kinks or corkscrew formations typical of the other polymers and thus handles more easily. It readily conforms to the tissue surface because it does not have a wiry springiness. The behavior of the polyethylene fiber at the eye of the needle illustrates its high flexibility: it can be tied to the needle with adequate security with a single throw. All three polymer sutures characteristically require a more complex knot because of the "unlooping" tension caused by their relative inflexibility.

The polyethylene fiber appears to have relatively low surface friction, and this agrees with measurements in a previous study that included polyethylene sutures.[21] Although the polyethylene fiber has a flat cross section, high flexibility, and relatively low friction, no difference from the other suture materials in pull-through resistance (tissue drag) could be detected in its passage through corneo-scleral or corneal tissue.

A definite limitation of the polyethylene fiber during its use in surgery was that it was undyed. For this reason it was used in 37-µm-wide ribbons that appear larger than 10-0 round monofilaments. Undyed 25-µm-wide polyethylene fibers were too fine for adequate visualization.

Finally, because of the polyethylene fiber's flat shape, its low friction, and its softness (with forceps compression it can become even flatter), handling the fiber requires tying forceps with jaws that properly appose in order to get enough traction for adequate tightening and tying tension. The characteristics that affect its tightening and tying, and its remarkable strength and flexibility, affect the cutting of it, and so sharp scissors with properly adjusted blades are necessary. Holding tension on the fiber makes it easier to cut because this prevents it from sliding between the scissors blades. Scissors used for cutting the polyethylene fiber tend to become dull sooner than when they are used for cutting the other polymer sutures.

Postoperatively.—Beginning the day after cataract surgery, from patients' descriptions of irritative symptoms and from slit-lamp evaluation of the response of conjunctiva, corneoscleral tissue, and iris, when it was sutured, no difference was distinguished in the biocompatibility of the polyethylene fiber when compared with the experience with the series of cataract operations in which the three commercially available polymer sutures were used. The polyethylene fiber provided good closure of the corneoscleral incision and resulted in the typical amount of early with-the-rule astigmatism that usually receded spontaneously to the desired level of less than 2 diopters. Occasionally, one or more of the limbs of the corneoscleral suture were cut with a blade fragment to relieve tension and reduce astigmatism, just as is done with sutures of the other polymers.

With the use of polyethylene fiber, rare instances were observed of spontaneous untying of the knot of the apposition suture or the beginning knot of the continuous corneoscleral suture, just as in the other series with the polymer sutures. But with the polyethylene fiber, the final knot of the continuous suture occasionally did spontaneously untie. The frequency of this phenomenon cannot be determined because of the variable visibility of corneoscleral sutures, especially of this undyed one. Untying of this knot was observed infrequently with the other, more visible, dyed polymer sutures: it is certainly more common with the polyethylene. When it was observed, this was generally a month or more after surgery. The explanation for this untying lies in the termination of a continuous chain suture: the knot is tied from the free end and a bight (a loop) drawn from the last limb,[22] resulting in a knot tied with three strands of the fiber instead of the usual two. Because of the high flexibility and low friction of the polyethylene fiber, two of the strands act like tracks, permitting the third to slip. In these instances, and throughout the entire series of cataract incisions closed with the polyethylene fiber, against-the-rule astigmatism that would occur with wound stretching was no more frequent than in the series in which sutures of the other three polymers were used.

A second occasional postoperative observation of both the continuous corneoscleral and keratoplasty sutures was the unravelling and exposure of exceedingly fine microfilaments from the edge of the fiber, usually within two months of surgery. This caused minor irritative symptoms that were eliminated by stripping the microfilament with a jeweler's forceps or cutting it with scissors; this had no effect on the security of the incision closure. Breakage of the fiber was never observed postoperatively.

After keratoplasty using the polyethylene fiber, from the first postoperative day, patients' complaints of irritation were much less than when this operation is performed using the other polymer sutures. Improved patient comfort continued even if an end of the single knot became exposed and also even when one or more limbs remained above the epithelial surface. This is due to its flat shape with a thickness of only several micrometers, its high flexibility, and its low friction. With the polyethylene fiber, knots are small and compact, and limbs readily conform to the shape of the corneal surface, lying flat up to each point of entry and exit. Suture-stimulated vessel ingrowth into the graft has not been observed, even where a knot or limb is exposed. Graft-host edge apposition is better controlled in the polyethylene fiber-sutured grafts, as indicated by fewer focal peripheral graft striae. This may be attributed to the fact that the fiber is very inelastic, which permits more precise estimation of suture tension during tightening.

COMMENT

There is good agreement between the results of the laboratory testing of the mechanical properties of the ultrastrong polyethylene fiber and the observations made during and after surgery. The polyethylene fiber has remarkably high tensile strength and

flexibility. Suture break as a factor during both cataract and keratoplasty surgery with this fiber is actually eliminated in all the manipulations a continuous suture is subjected to—a most unusual attribute in an ophthalmic suture. Further, it is very inelastic in comparison with the other suture materials, and this permits especially sensitive control during suture tightening and tying. This characteristic is especially advantageous in keratoplasty because the graft position is critically dependent on the suture. In both the laboratory testing and in use during surgery, the polyethylene fiber showed great flexibility, a valuable attribute that gives it what surgeons of the premicrosurgery era would describe as "hand" superior even to the standard of that period—silk.

The knot pull strength of the polyethylene fiber is also high, which indicates the potential for superiority over conventional polymer sutures in the important aspect of knot security. Although laboratory testing showed that the polyethylene fiber has a somewhat lower knot holding strength with simpler knots than the other three polymers, more complex knots than are commonly used would realize polyethylene's great knot pull strength. Considering the surprising security of this fiber when tied to an eyed needle with only a single throw, the conventional knot testing procedures may not provide a full characterization of the complex aspect of knot security.

Postoperatively, in cataract incision closure the polyethylene fiber showed the same biocompatibility characteristics as the sutures currently being used. The one situation in which knot security with the polyethylene is different from the other sutures was the occasional observation of knot slippage where three strands of the fiber are included in the knot of a continuous cataract incision closure suture, but this did not affect the security of incision closure.

Postoperatively, in keratoplasty the polyethylene fiber seems superior in every way to the commercially available sutures. Considering biocompatibility to include the effects on ocular tissue of its flat shape, high flexibility, and low surface friction, this fiber is superior as a suture for keratoplasty.

A minor inconvenience is the occasional unravelling of microfilaments from the fiber, sometimes causing irritation until they are removed. And obviously, this fiber is more difficult to work with because it is undyed. Whether the polyethylene fiber will biodegrade over time cannot be determined at this time because of the limited period of follow-up; no evidence of it has been observed to the present.

Further refinements in the process of preparation of the ultrastrong polyethylene fiber may lead to its acceptance as an ophthalmic microsuture. First, it will be much easier to see during surgery because it has been successfully dyed so that 25-μm-wide ribbons of it are as visible as 10-0 polypropylene (unpublished results). Second, the use of a "gel-spinning" process should yield a fiber with a more compact filament structure and thus eliminate the occasional unravelling of microfilaments.[8,23] Finally, to increase the polyethylene fiber's surface friction, its surface texture might be improved by surface structurization.[24]

The authors do not have any commercial or proprietary interest in the ultrastrong polyethylene fiber discussed in this article and had no financial interest as evaluators of the ultrastrong polyethylene fiber.

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HERMES DECLARATION
EXHIBIT 17

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(12) **United States Patent**
Grafton et al.

(10) **Patent No.: US 6,716,234 B2**
(45) **Date of Patent: Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

(75) Inventors: **R. Donald Grafton**, Naples, FL (US); **D. Lawson Lyon**, Exeter (GB); **Brian Hallet**, Taunton (GB)

(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **09/950,598**

(22) Filed: **Sep. 13, 2001**

(65) **Prior Publication Data**

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(51) **Int. Cl.**[7] **A61L 17/04**
(52) **U.S. Cl.** **606/228**
(58) **Field of Search** 606/228

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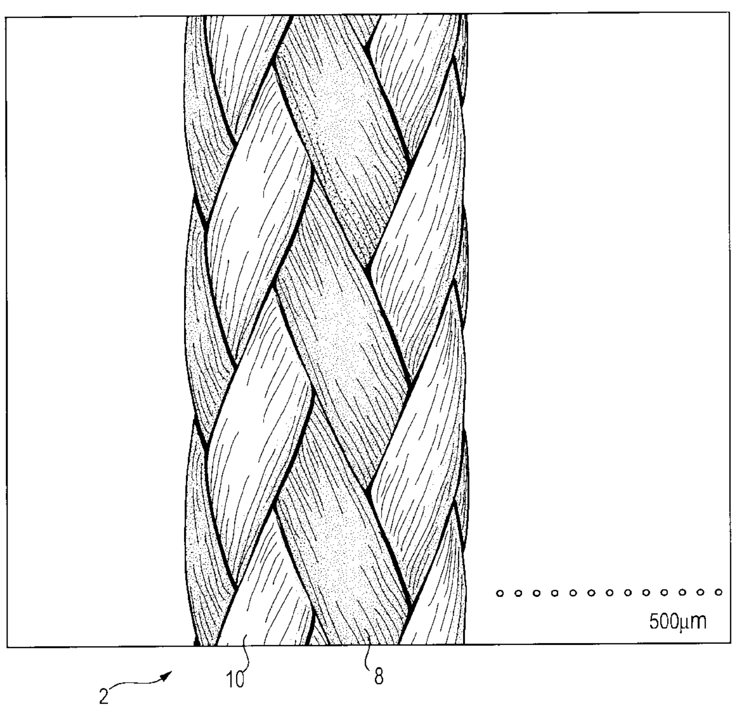
Primary Examiner—David O. Reip
(74) *Attorney, Agent, or Firm*—Dickstein Shapiro Morin & Oshinsky, LLP

(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets



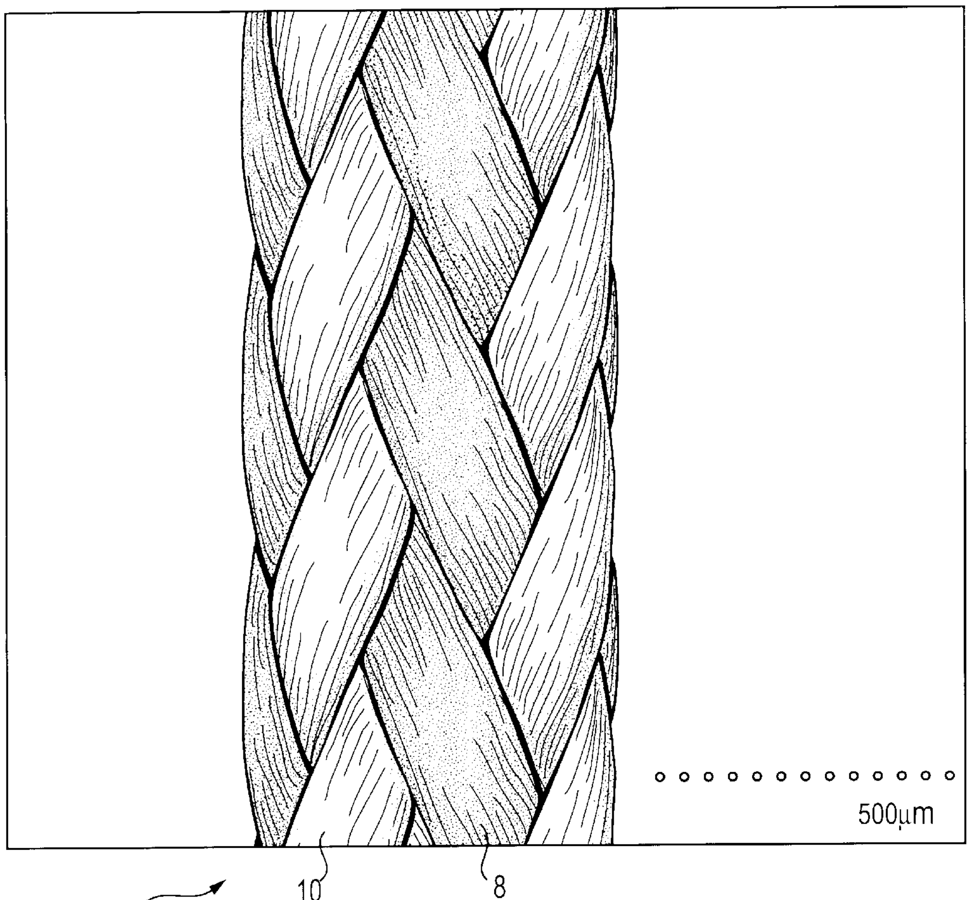


FIG. 1

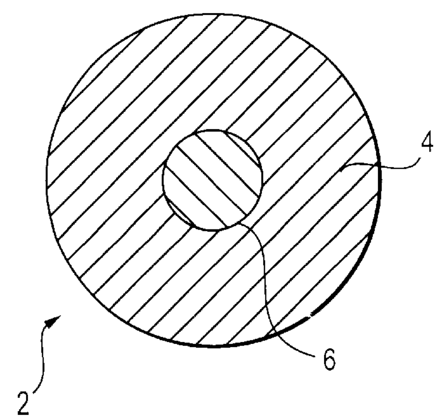


FIG. 2

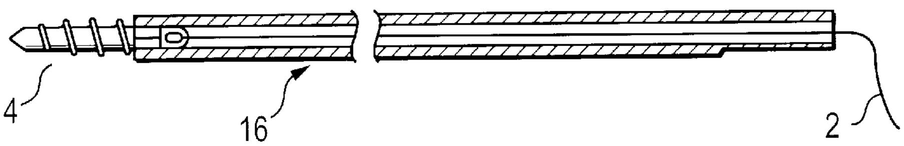


FIG. 3

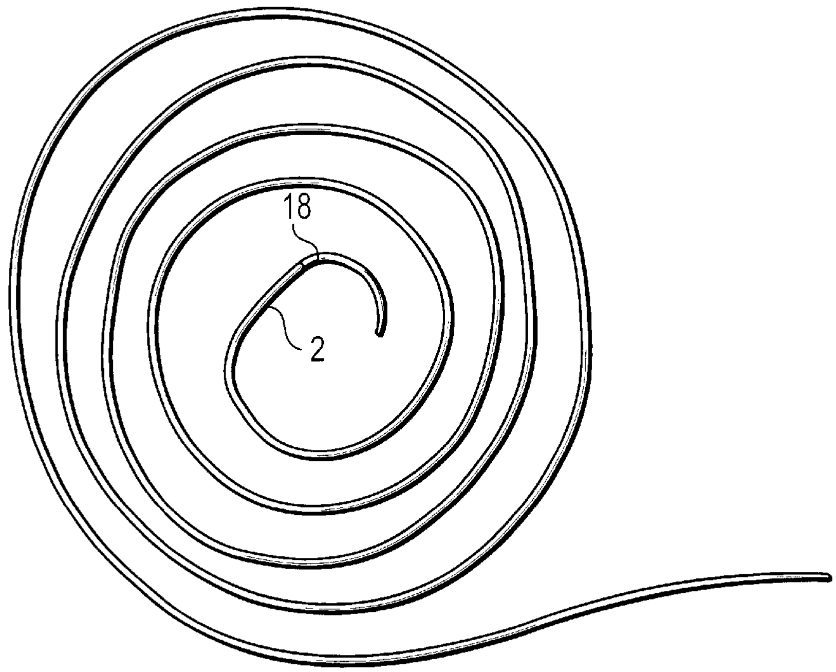


FIG. 4A

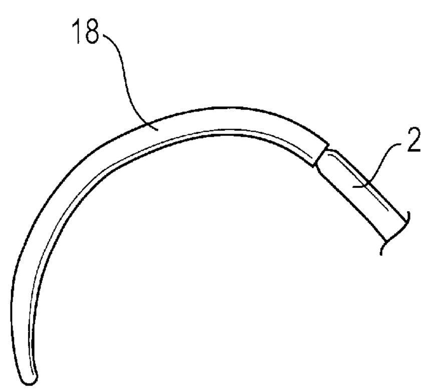


FIG. 4B

HIGH STRENGTH SUTURE MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. **1** is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. **2** is a schematic cross section of a length of suture according to the present invention.

FIG. **3** is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. **4**A and **4**B show the suture of the present invention attached to a half round, tapered needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, a scanning electron micrograph of a length of suture **2** according to the present invention is shown. Suture **2** is made up of a cover **4** and a core **6** surrounded by the cover. See FIG. **2**. Strands of ultrahigh molecular weight polyethylene (UHMWPE) **8**, sold under the tradename Dyneema or Spectra, and strands of polyester **10** are braided together to form the cover **4**. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture **2** is attached to a suture anchor **14** as shown in FIG. **3** (prepackaged sterile with an inserter **16**), or is attached to a half round, tapered needle **18** as shown in FIGS. **4**A and **4**B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim **1**, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim **1**, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim **1**, wherein the core comprises a bout 30% of the filament.

5. The suture filament of claim **1**, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim **1**, further comprising a coating disposed on the cover.

7. The suture filament of claim **1**, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a)
Massachusetts corporation,)
Plaintiff,) Civil Action
vs.) 04-12457 PBS
ARTHREX, INC., a Delaware)
corporation,)
Defendant.)

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The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

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182

Q. Okay. Do you understand this is the prosecution history of a -- of an Arthrex patent, right?
A. Yes, that's what it says.
Q. Okay. If you would turn to DMI 41091.
A. 41091, yes.
Q. Okay. At the top paragraph, do you see it says, "The suture of Example 7 of Chesterfield, et al., '575, uses a Spectra 1000 core surrounded by a hollow sheath --" I'm sorry, "a hollow braided sheath made of a single type of yarn"?
Do you see that?
A. No, where are you, starting in the middle?
Q. Right here. Right here, first paragraph.
A. First paragraph.
Q. This says --
A. Suture Example 7, is that what you're reading from?
Q. Yes, the suture --
A. Okay.
Q. Do you see that?
A. Yes, I see it.
Q. It says, "The suture of Example 7 of Chesterfield, et al., '575, uses a Spectra 1000 core surrounded by a hollow braided sheath made of a single type of yarn."
Do you see that?
A. Um-hum.
Q. Do you agree with that statement?
A. Yeah.
Q. Okay. And then if you go down later in the third paragraph --
A. Third paragraph, yeah.
Q. -- it says, the second sentence says, "As noted above, Chesterfield, et al., '575, does not disclose an example of a braided sheath that includes a blend of both -- of both ultra high molecular weight polyethylene and polyester."
Do you see that?
A. Yes.
Q. Do you agree with that statement?
A. Yes.
Q. Okay. When you were referring to the claims of the '575 patent -- I'd like to turn to those now.
A. Are you done with this or --
Q. Yes.
A. Number 4, the '575.
Q. It claims that it's a method for repairing split portions of body tissue. Do you see that?

184

A. Yes.
Q. It goes on, it says, "comprising looping a flexible elongated member about the body tissue."
Do you see that?
A. Um-hum.
Q. Okay. What significance do you give to the meaning of going "about" the body tissue? What does that mean?
A. It --
MR. TAMBURO: Objection, vague.
THE WITNESS: "About the body tissue" is kind of funny language. Through the tissue, that's what it normally will do to produce --
BY MR. BONELLA:
Q. You mean going through the tissue?
A. That's what I would think.
Q. Okay.
A. Whether soft or hard, doesn't matter.
Q. Do you think the -- where the claim says "looping a flexible elongated member about the body tissue," do you think that FiberWire is used in going about body tissue as that's used in the claim?
A. You're asking about FiberWire?
Q. Yes.

185

MR. TAMBURO: Objection, vague, and he's not an expert on how FiberWire is used in surgery.
THE WITNESS: Again, I may not know what's in surgery, but I have myself used in meniscal repair with a surgeon through the body tissue.
BY MR. BONELLA:
Q. Okay. So, is FiberWire -- to the extent you know, if FiberWire is used in surgery, is it used to go about body tissue?
A. To attach something, yes.
Q. It is? Okay. Would that be a pretty standard understanding?
A. I don't know what is standard. It's new suture, so nobody might not know that it's available. It cannot be standard.
Q. Well, no, not the FiberWire. Are sutures --
A. You asked me for FiberWire first, then you changed --
Q. The use of FiberWire, not the construction, how it's used.
A. Yeah.
Q. FiberWire, is it your understanding that it's normally used to go about body tissue?
MR. TAMBURO: Objection, vague, and he's

238

A. Then polypropylene is twice, polyester is about twice -- I mean polyester -- polyethylene is twice, then -- ultra high molecular weight polyethylene is twice than polypropylene and twice than polyester, so they are probably significantly higher for the ultra high molecular weight polyethylene, knot pull strength.
Q. Do you know if -- does he provide the standard deviation for the knot pull strength?
A. He didn't, but just looking at the figures, I mean, I can say that, looking at 1.35 or 1.44, you have to say that.
Q. Okay. So, he did not provide standard deviation in this chart.
A. Not in this chart.
Q. Now, for the knot configuration four equals one equals one, do you see that?
A. Yes.
Q. The polyethylene failed at 0.35 gigapascals, which is lower than the failure value for the nylon, polypropylene and polyester for the four equals one equals one configuration, right?
A. Yes.
Q. Okay. And that's because the polyethylene slipped, right?

239

A. I don't use the word "sucked."
Q. I said "slipped."
A. Slipped, okay. I thought I heard... sorry.
Q. So, the polyethylene failed at the 0.35 gigapascal level for the four equals one equals one configuration because of the polyethylene slipping, right?
A. Right.
Q. Okay. Polyethylene, including ultra high molecular weight polyethylene, is a lubricious material, right?
A. Yes.
Q. Okay.
A. It's also polypropylene -- excuse me.
Q. Sure.
A. Polypropylene is also a lubricious material.
Q. It is?
A. Yes, it is.
Q. Okay. How about nylon or polyester, are they lubricious?
A. Nylon is also -- again, is lubricious.
Q. How about polyester?
A. Polyester will be less.

240

Q. And nylon is less lubricious than polypropylene and polyethylene, right?
A. Probably.
Q. Okay. Now, in that chart, do you see how going across there's different knot configurations, two equals two, three equals two equals one, four equals one equals one, four equals four and four equals four equals four?
A. Yes.
Q. So, going from left to right, two equals two to four equals four equals four, the two equals two is a simpler knot than the four equals four equals four, right?
A. It's not simple or complex. It depends on what the surgeon wants to do. So, he can put more knots to make sure, and in general, they do. They will not stop at two by two. They will probably go to four by four by four to make sure it is there, especially ophthalmic use.
Q. Okay. And if you turn to page ARM 25137 --
A. Thirty-seven, yeah.
Q. Okay, of Cohan, the last paragraph of the first column --
A. Yeah.
Q. -- do you see the sentence beginning

241

"Although"? The first column --
A. Did you say first column?
Q. First column, last paragraph.
A. Last paragraph.
Q. The sentence beginning, "Although."
A. "Although," yes.
Q. Cohan states, "Although laboratory testing showed that the polyethylene fiber has a somewhat lower knot holding strength with simpler knots than the other three polymers, more complex knots than are commonly used would realize polyethylene's great knot pull strength."
Do you see that?
A. Yes.
Q. Okay. So, Cohan was calling the more -- the additional knot configurations more complex, right?
A. That's what -- if he meant by that.
Q. Well, did you understand that's what he means when you read this reference?
A. Well, I -- I think that normally for a surgeon, they will put as many knots they can to make sure it's secure, and it's nothing complex or simple about it.
Q. Well, if you look at the author, the author

294

in the monomer?
A. Yeah -- well, it's not a monomer, in the polymer.
Q. In the polymer?
A. Yeah.
Q. I'm confused. Are you saying that the monomer unit in all types of polyethylene is the same or different?
A. Mostly same, yeah.
Q. Mostly same, okay.
Would one of ordinary skill in the art between 1988 and 1992 think that the term "polyethylene" refers to low-density polyethylene or includes -- should I say includes low-density polyethylene?
A. Yeah, it would.
Q. It would? But not ultra high? Is that your opinion?
A. Ah, they will also include ultra high, because there are different properties, so they will include also ultra high, as well as low-density.
Q. Okay. I'd like to turn to polypropylene as used in the '446 patent, Exhibit 3 to your first report. Do you see the '446 patent?

295

A. Yeah.
Q. Exhibit 3?
A. Exhibit 3.
Q. Right.
A. Yeah, I'm at this.
Q. No, Exhibit 3. I'm sorry, that's Exhibit 3. I'm sorry. Yeah, if you would go to column 4, please.
A. Yeah.
Q. Okay. Beginning at line 9 through 32, do you see that?
A. Nine through 32, yeah.
Q. Okay. That paragraph says, "Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers."
Do you see that?
A. Yes.
Q. Is ultra high molecular weight polyethylene a nonabsorbable polymer?
A. Yes.
Q. Okay. Then it says, "In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the pliability, or compliance, and surface lubricity of the

296

heterogenous braid."
Do you see that?
A. That is correct.
Q. Ultra high molecular weight is a lubricating yarn, right?
A. Yes.
Q. Okay. Then it says -- further down it says, "Such fiber forming polymers include perfluorinated polymers," and describes some of those, and then it says, "as well as non-perfluorinated polymers," and refers to polyethylene and PE, right?
A. Right.
Q. Okay. Ultra high molecular weight polyethylene came as fibers before 1992, right?
A. Yes.
Q. Okay. Now, do you see where in the end it says, "The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP"?
Do you see that?
A. Yes.
Q. Okay. That's column 4, lines 28 to 31.
Did you understand that sentence to refer to all types of polypropylene or just certain types of polypropylene?

297

MR. TAMBURO: Objection, vague.
THE WITNESS: This is general purpose polyethylene, which it provides the lubricity and as well as pliability and compliance, not ultra high molecular weight polyethylene.
BY MR. BONELLA:
Q. Okay, that wasn't my question. Listen to the question.
Did you understand that sentence to refer to all types of polypropylene?
MR. TAMBURO: Objection, vague.
THE WITNESS: The fiber-forming polypropylene, yes.
BY MR. BONELLA:
Q. All types, okay.
Did you understand -- do you see where it refers to PVDF?
A. Yes.
Q. Did you understand this paragraph to be referring to all types of polyvinylidene fluoride?
A. Yes.
Q. Okay. Do you see where it refers to PTFE in that paragraph?
A. Yes.
Q. Did you understand it to be referring to

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts Corporation,)
Plaintiff,)
v.)
ARTHREX, INC., a Delaware Corporation)
Defendant.)

Videotaped Deposition of DEBI PRASAD MUKHERJEE
- VOLUME TWO -
Washington, DC
Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

Page 550

Q But for known suture materials, the sterilization parameters for ethylene oxide are well-known to one of ordinary skill in the art?
A For the suture that are currently used. But new suture like the ones described '446, there isn't, at least my opinion. One has to run the test to find out if there is or there isn't.
Q Well, sterilization of -- of PET was known, right, in 1988, of PET for fibers for sutures was well-known with ethylene oxide, right?
MR. TAMBURO: Objection, vague.
A Yes.
BY MR. BONELLA:
Q Okay. And sterilization procedures for PTFE were -- with sterile -- with ethylene oxide were well-known in 1988, right?
MR. TAMBURO: Objection, vague.
A It's also known, yes, but it -- it is also known that PTFE properties are affected by gamma radiation.
BY MR. BONELLA:
Q But ethylene oxide was known in 1988 that they are --
A Yes.
Q -- generally substantially not affected?

Page 551

A Yes.
MR. TAMBURO: Objection, vague.
BY MR. BONELLA:
Q I'd like to turn to your rebuttal report, which is Exhibit 356. Page 18, you talk about the Harpell patents.
A Yes.
Q Did you consider in your analysis whether the Harpell patents disclose a coated suture?
MR. TAMBURO: Take your time to read the report if you need to.
A To best of my recollection, it didn't.
BY MR. BONELLA:
Q Okay. Well, if the Harpell patents did describe coated sutures, would that change your opinion?
A Yeah.
Q Why?
A Because was refer -- I mean, the coating is an issue, whether coating does or does not change properties of this material.
MR. BONELLA: Okay. I'd like to ask you about some other issues. Let's take a quick break. I need to organize myself.
THE VIDEOGRAPHER: You're now going off

Page 552

the video record at 12:01 p.m.
(A recess was taken from 12:02 p.m. through 12:14 p.m.)
THE VIDEOGRAPHER: We're now back on the video record. The time is 12:14 p.m.
BY MR. BONELLA:
Q Dr. Mukherjee, did the three reports that you provided in this case contain all the opinions that you have in this case?
A At this moment, yes.
Q Okay. Have you been asked to develop any other opinions?
A No.
Q Okay. Are you an expert in the area of suture design?
MR. TAMBURO: Objection, vague.
A Yes.
BY MR. BONELLA:
Q And what -- what's your basis for saying that?
A I work in suture industry more than 13 years.
Q Okay. And when -- you stopped working in the suture industry in the '80s?
A '87.

Page 553

Q Okay. And are you still expert in the area of suture design today?
MR. TAMBURO: Objection, vague.
A Yes.
BY MR. BONELLA:
Q Even though you haven't worked in the industry?
A But I have worked on projects involving sutures in LSU.
Q Okay. Going back to sterilization for a minute, the Cohen reference, remember Cohen?
A Yes.
Q Does Cohen describe how to sterilize the suture that he made?
A Yes, he did.
Q In the -- in the document? So would -- so would --
MR. TAMBURO: If you need to review it, review it.
BY MR. BONELLA:
Q So is that a sterilization for an -- the ultra high molecular weight polyethylene monofilament suture that he described?
A That was one of -- let me look at that.
Q Excuse me?

MR. TAMBURO: Objection, vague.
A Enough information for a scanning microscopy is not very conclusive. They may or may not be.
BY MR. BONELLA:
Q You don't know?
A I don't know.
Q Okay. Does the coating on FiberWire prevent the PET yarns and the PTFE yarns from each providing their individual properties to FiberWire?
MR. TAMBURO: Objection, vague.
THE WITNESS: Now please correct me.
MR. TAMBURO: And -- and -- and -- and --
THE WITNESS: FiberWire does not contain a PTFE.
BY MR. BONELLA:
Q Oh, I'm sorry. Did I misspeak?
A You just said that.
Q I'm sorry.
Does the coating on FiberWire prevent the PET fibers, PET or ultra high molecular weight polyethylene fibers from providing contribution to FiberWire's properties?
MR. TAMBURO: Objection, vague.
A No.

BY MR. BONELLA:
Q Okay. I'd like to go to your first report, invalidity, Exhibit 239. If we go to tab -- tab 9 --
A Tab 9.
Q There's an excerpt from Dr. Steckel's report.
A Right.
Q It's only a -- a one-page excerpt from his laboratory notebook.
A Yes.
Q Okay. Did you select that one page to put in your report out of his entire notebook, or were you given that one page?
A No, I have the entire notebook.
Q Okay. Why'd you pick -- did you consider the remainder of his notebook when -- when you select that individual page to attach to your report?
MR. TAMBURO: Objection. Well, not an objection, but if you need -- to the extent you need to read the context of why you cited this, please do so.
A Because it is very clear that he was talking about difficulties in core popping and braid looseness.

BY MR. BONELLA:
Q Okay. Do you know what samples on that page he was talking about, when -- when they were made?
A Well, according to the lab, his notebook page signed was date of '89 -- I mean '89.
Q Right.
A That's what it says here.
Q Okay. Do you know when those samples were made that are discussed on that page?
A It's February 2, 1989 at the top. That's when the lab entry is.
Q Okay.
A I assume that's when the samples were made.
Q Okay. I'd like you to turn to Exhibit 26 to Exhibit 359, the report of Dr. Matthew Hermes, which contains a larger excerpt of Dr. Steckel's report right here. And if I could draw your attention to page DMI002617, okay?
A Right here.
Q Right here. 17. Okay --
A 1617.
Q Here's an entry on DMI002617 is June 6, 1988?

A That's correct.
Q Okay. And if you look at the next page, shows a chart of samples, composite braid evaluation, braid constructions. Do you see that?
A Yes.
Q Did you consider that, those constructions?
MR. TAMBURO: Take your time, Dr. Mukherjee.
A I believe I did.
BY MR. BONELLA:
Q Okay. CBE15, do you see CBE15 sample?
A Yeah.
Q Do you know what the construction of that sample was?
MR. TAMBURO: Objection, vague.
A Was PTFE, 11049 in the denier and the fiber. This column on these other things are not there.
BY MR. BONELLA:
Q Do you know what the construction of CB15 was?
MR. TAMBURO: Objection, vague.
A If I understood, you are asking the --
BY MR. BONELLA:

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(71) Applicant: BIORESEARCH INC. [US/US]; 315 Smith Street, Farmingdale, NY 11735 (US).

(72) Inventors: KURTZ, Leonard, D., Dr. ; 46 Woodmere Boulevard, Woodmere, NY 11598 (US). ARONOFF, Marvin ; 161-18 65th Avenue, Flushing, NY 11365 (US).

(74) Agent: SARRO, Thomas, P.; Larson and Taylor, 727-Twenty-Third Street, South, Arlington, VA 22202 (US).

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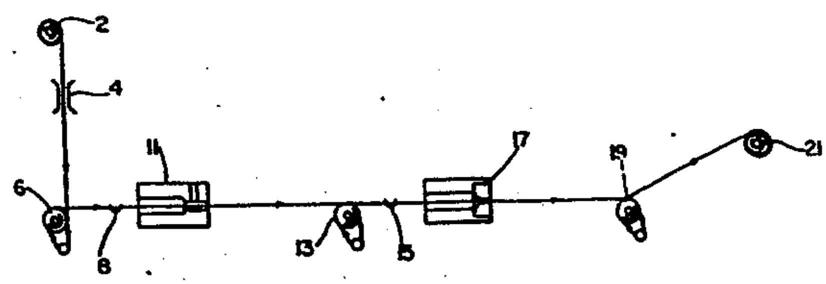

(57) Abstract

A composite surgical suture of extraordinary high knot strength and capable of use over a range of United States Pharmacopeia (USP) suture sizes is prepared by coating or covering a core of a fiber-forming synthetic polymer material having a knot tenacity of at least 7 grams per denier with a conventional suture material. Illustrative of suitable core materials are Kevlar and high strength fully chain-extended crystalline polyethylene.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000150

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000151

COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to improved surgical sutures having extremely high knot strength and to methods for their preparation. More particularly, the invention is directed to composite surgical sutures having a knot strength that enables them to be used over a range of suture sizes classified by the United States Pharmacopeia (USP).

Brief Description of the Prior Art

Surgical sutures are generally divided into two broad classes: (1) absorbable sutures, either natural or synthetic, which are absorbed by the body and (2) non-absorbable sutures, which remain in the body for prolonged periods of time or are removed when the wound heals.

From the patient's viewpoint, whether an absorbable or non-absorbable suture is employed, assuming no toxicity of the suture implant, it is a surgical dictum that the finest suture should be used and that the knot should have the least mass. This dictum is based upon the belief that problems in suture implants are directly related to the size of the suture and the bulk of the mass, i.e., the larger the bulk, the greater the probability of trouble in healing.

Undoubtedly, this was the rational for the original establishment of the USP classification which divides non-absorbable sutures into seventeen sizes: 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7. A few additional

sizes are used which are not USP. Considering that silk was the most widely used non-absorbable suture in the mid-twenties and thirties, this size differentiation was based upon manufacturing. These seventeen sizes could be differentiated one from another by eye. If a finer differentiation were desired, it would not be accomplished becasue of the variation in the raw material as extruded by the silk worm. This classification has been quite useful. Obviously, the number of sizes cannot be considered "standardization" by any means. The sizes are numerous. Unfortunately, it has not been possible to coalesce size because the finer sizes do not have the adequate knot break strength to substitute for the next size.

A further long term problem in surgery is post-operative hernia. It is a truism that scar tissue never achieves the tensile strength of normal tissue. Hernias have occurred many years post-operably through the scar. If a suture were developed which would leave as a residue a non-absorbable suture to support that scar tissue, it would undoubtedly decrease and most likely eliminate the post-operative hernia as a complication.

Composite sutures having a reinforcing core are known in the prior art. None, however, achieve the aforementioned characteristics desired in a suture.

Accordingly, it is an object of the invention to provide a surgical suture with knot strengths so great that suture of much less foreign material is left in the body.

Another object of the invention is to provide a surgical suture having a knot strength that renders it useful over a range of surgical sizes within the USP classification of graded suture sizes, and thus

having the ability to replace the USP graded scale of sizes with just a few finer sutures whose strength would cover the entire range.

A further object of the invention is to provide a composite suture which leaves a residue of non-absorbable suture to support scar tissue and, therefore, decreases or eliminates post-operative hernia as a complication.

Another object of the invention is to provide a method of preparing surgical sutures having extremely high knot strength whose surface characteristics can be tailored to meet desired properties.

A further object of the invention is to provide composite sutures capable of using needles which more closely approximate the outer diameter of the suture.

A further object of the invention is to provide a composite suture having lateral strength, that is, a suture stabilized against abrasion, kinking and/or fibrillation during knotting.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by a sterile, surgical suture having an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier coated with a film and fiber-forming surgical material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

The elongated core of the sutures of the invention can be formed of any fiber-forming synthetic polymer, such as a polyamide, polyolefin, polyester

and the like, having a straight pull tenacity of at least 15 grams/denier, preferably up to 70 or more grams/denier and a knot tenacity of at least 7 grams/denier, preferably up to 30 or more grams/-denier. By "knot tenacity" as used herein and in the appended claims is meant knot break strength divided by the denier. Unless the synthetic polymer making up the suture core of the invention meets the aforementioned knot tenacity properties, the resulting coated core fails to provide a suture which achieves the desired objects of the invention.

Illustrative of synthetic polymer materials suitable for use as the core of the suture of the invention are fiber-forming aromatic polyamides in which the chain extending bonds from each aromatic nucleus are essentially coaxial or parallel and oppositely directed. The term "aromatic nucleus" is used herein to include individual enchained aromatic rings and fused-ring aromatic divalent radicals. The preferred polymers include carbocyclic aromatic polyamides containing up to 2 aromatic rings, including enchained non-fused rings (e.g. 4, 4'-biphenylene) or fused rings (e.g. 1, 5-naphthalene) per amide linkage. The chain-extending bonds from these aromatic rings are para-oriented and/or essentially coaxial or parallel and oppositely directed.

Highly preferred polyamides are characterized by recurring units of the formula:

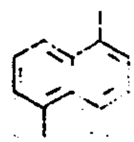
$$\text{(I)} \qquad \left[\overset{O}{\overset{\|}{C}} - R - \overset{O}{\overset{\|}{C}} - \underset{}{\overset{H}{\overset{|}{N}}} - R' - \overset{H}{\overset{|}{N}} \right]$$

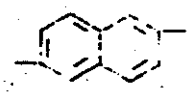
wherein R and R' (when the chain extending bonds are essentially coaxial) are selected from the group of:

 1,4-phenylene, and

 4,4'-biphenylene

and R and R' (when the chain extending bonds are essentially parallel) are selected from the group of:

 1,5-naphthylene, and

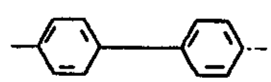
 2, 6-naphthylene

R and R' may be the same or different and may contain substituents on the aromatic nuclei.

Additional highly preferred polyamides of this invention are characterized by recurring units of the formula:

(II) $$\left[\overset{\displaystyle O}{\overset{\|}{C}} - R'' - \overset{\displaystyle H}{\overset{|}{N}} \right]$$

wherein R" is selected from the group of:



Similarly R" may contain substituents on the aromatic nuclei.

As previously stated, the aromatic nuclei of the polymers of this invention may bear substituents. These substituents should be non-reactive during the polymerization and preferably also should be non-reactive (e.g. thermally) during subsequent processing of the polymer, e.g., heat treating of a shaped fiber thereof. Such reactivity is undesirable in that it may cause cross-

linking of the polymer and may adversely effect the dope and/or fiber properties. Among the preferred non-reactive substituents may be names halogens (e.g., methoxy and ethoxy), cyano, acetyl, and nitro. Other suitable substituents non-reactive during the polymerization will be evident to those skilled in the art and are contemplated herein provided such do not adversely affect the desired properties of the dopes and/or fibers of this invention, e.g., due to factors such as steric hindrance. Generally, it is preferred that no more than two (and more preferably no more than one) suitable substituents be present per aromatic nucleus. However, more than two such substituents may suitably be present if the substituent is a relatively small group e.g., methyl.

Both humo-and co-polyamides having substituted or unsubstituted aromatic nuclei, as described above, are well suited for the dopes and fibers of this invention. Random copolymers are preferred copolymers. By the term "random" is meant that the copolymer consists of molecules containing large numbers of units comprised of two or more different types in irregular sequence. The units may be of AB (e.g., from p-aminobenzoyl chloride hydrochloride), AA (e.g., from p-phenylenediamine or 2,6-dichloro-p-phenylene diamine), or BB (e.g., from terephthaloyl or 4,4'-bibenzoyl chloride) type or mixtures of these, provided always that the requirements of stoichiometry for high polymer formation are met. It is not necessary that the relative numbers of the different types of the unit be the same in different molecules or even in different portions of a single molecule.

One or more of these polymers may suitably be

used in the fibers of this invention, i.e., a single homopolymer; a single copolymer; or homopolymer and/or copolymer blends are suitable herein.

While the polymer chains described above consist essentially of amide links (- CONH -) and aromatic ring nuclei as described above, the polymers useful for preparing the core of this invention may also comprise up to about 10 percent (mole basis) of units not conforming to the above-cited description, e.g., aromatic polyamide-forming units whose chain extending bonds are other than coaxial or parallel and oppositely directed, e.g., they may be metaoriented, or of linkages other than amide, e.g., urea or ester groups.

Among the suitable aromatic polyamides may be named poly(p-benzamide); poly(p-phenylene terephthalamide); poly(2-chloro-p-phenylene terephthalamide); poly(2,6-dichloro-p-phenylene 2,6-naphthalamide); poly(p-phenylene p;p'-biphenyldicarboxamide); poly(p,p'-phenylene benzamide); poly(1,5-naphthylene terephthalamide); ordered aromatic copolyamides such as e.g., copoly(p,p'-diaminobenzanilide terephthalamide), and random copolyamides such as, e.g., copoly(p-benzamide/m-benzamide) (95/5); and many others.

These aromatic polyamides generally have an inherent viscosity and prefereably greater than 1.0. Inherent viscosity (ηinh) defined by the following equation:

$$\eta inh = [\ln (\eta rel)/C]$$

wherein (ηrel) represents the relative viscosity and C represents a concentration of 0.5 gram of the polymer in 100 ml of solvent. Exemplary of such aromatic polyamides are those known as the "Kevlar"

series, products of the DuPont corporation, which generally have a straight pull tenacity of about 18 to 25 grams per denier and a knot tenacity of at least about 7 grams per denier. Further examples of such aromatic polyamides and their methods of preparation can be found, for instance, in U.S. Patent Nos. 3,063,966, 3,600,350, 3,671,542 and 3,919,587 all incorporated herein by reference.

Another example of a synthetic polymer suitable for use as the core of the suture of the invention are high strength polyolefins such as polyethylene which provides fibers having a straight pull tenacity of about 25-50 grams/denier and a knot tenacity of about 7 to 17 grams/denier. These polyolefin fibers are characterized by full chain extension and high crystallization and can be prepared: (1) by ultradrawing of the solidified crystalline polyolefin material that is, by further development of the traditional cold drawing process, and (2) by extending the chains in random state (melt or solution) and inducing them to crystallize in the extended form subsequently. Polyolefins having these characteristics and their method of preparation are described in Keller, A. and Barham, P.J. "High Modulus Fibres", Plastics and Rubber International, February, Volume 6, No. 1 (1981), herein incorporated by reference.

The core of the surgical suture of the invention can be either a monofilament or of multifilament construction. The latter is ordinarily preferred since the coating of suture material subsequently applied generally exhibits stronger adhesion to multifilament cores. The liquified suture material coating tends to penetrate and fill the interstices of a multifilament core as well as

coating the core, thereby anchoring the coating thereto. Multifilament cores can take the form of braids, twisted polyfilaments, yarns and the like.* It should be noted that while the synthetic polymer materials contemplated for use as the core of the composite sutures of the invention, have high axial strength, they are not ordinarily suitable for use as sutures since they do not possess the necessary lateral strength and, therefore, tend to abrade, kink and/or fibrillate during knotting. Coating of the core with a suture material pursuant to the present invention has been found to unexpectedly stabilize, i.e. provide lateral strength resistance against such action thereby rendering suitable for use as sutures these synthetic polymer fibers normally unsuitable for such use.

The surgical suture material used to coat the core can be any film-forming material commonly used in the construction of absorbable and non-absorbable sutures. In general these suture materials when drawn into fibers exhibit straight tensile strengths of about 4 to 10 grams/denier. Examples of the non-absorbable type suture materials are silk (fibroin), polyolefins, such as polyethylene and polypropylene, polyesters such as polyethylene terephthalate and nylon. Examples of absorbable type materials useful as the coating for

* The suture material in the form of multi or monofilament yarn may also be present initially as a core around which the high strength yarn which eventually becomes the core in the finished suture is braided or twisted or it may be formed into a plied, twisted, braided or co-mingled construction with the high strength yarn.

the core include collagen and the synthetic absorbable materials such as polylactide, polyglycolide and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Patent Nos. 3,636,952 and 2,683,136, which patents are herewith incorporated by reference. Such synthetic absorbable polymers are sometimes referred to herein as simply homopolymers and copolymers of lactide and glycolide.

The amount of suture material coated onto the core will vary depending upon the constructon of the core, whether monofilament or multifilament, the number and tightness of braid or twist, the particular tensile strength and knot tenacity of the core, the particular suture material used as the coating and its nature, e.g. melt, solution or solid. In general, when the coating is a nonabsorbable suture material, the coating will constitute about 5 to about 10% by weight of the coated core. On the other hand, when the coating is an absorbable suture material, the coating may constitute about 5 to 90% by weight of the coated core.

The coatings can be applied by a variety of suitable techniques well known in the coating art. For example, the coatings can be applied to the core by solution coating, melt coating, extrusion coating and the like.

In melt coating, for example, the uncoated core under tension is slowly passed through a melt of the suture material and then through a die having an orifice smaller than the upper diameter specification for the suture size desired, heated above the melting point of the coating materials, to trim

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000161

off excess coating material and shape the composite. Multiple coatings may be applied if necessary.

In solution coating, the suture material is dissolved in a suitable solvent and the core is slowly passed through the coating solution thus formed. The treated core is then passed continuously through a tubular oven heated to an elevated temperature to evaporate the solvent and coalesce and solidify the suture material that remains.

A preferred coating technique when the core being coated is of multifilament construction comprises initially either solution coating or melt coating the multifilament core while the latter is held under a suitable tension and allowing the liquified coating material to penetrate or infiltrate the interstices of the core, thereby forming roots which help anchor the coating of the core. A second layer of the same suture material may then be applied to the impregnated core by any of the conventional coating methods.

In a typical extrusion coating process the core is passed through the cross-head die of a conventional wire coating extrusion apparatus. Pellets of the coating material are introduced into the plastification zone of the extruder wherein they are plasticized into a melt which is forced through the annular die of the extruder and onto the core.

Which coating technique is employed will usually depend upon the particular core utilized. Aromatic polyamide cores, for example, lend themselves to melt or extrusion coating because of their high melting points. The high strength polyethylene cores, on the other hand, have

relatively low melting points, e.g. about 145°C, and must be treated differently. With them, solution coating of the monoor multi-filament cores is the chief method.

According to a preferred embodiment of the invention, when the core being coated is an aromatic polyamide, it is subjected to both a precoating stage and finish coating stage, each of which will be discussed below in more detail.

Impregnation/Precoating Stage

The impregnation/precoating operation of the invention can be conducted using a thread composed of a core made up of multifilaments of a suture material and a plurality of fibers of a synthetic polymer having a tenacity of at least 18 grams/-denier and knot tenacity of at least 7 grams/-denier. The thread can be formed in the usual manner as by twisting, braiding, etc., a plurality of the synthetic polymer fibers around the suture material core. The thread, that is, the covered core is then heated to temperatures above the melting point of the multifilament core material passing it through any suitable oven during which passage the suture material melts and under the tension developed and/or applied exudes upward through the polyfilamentous synthetic polymer component and onto its surface. The amount of coating employed should be sufficient to not only fill all the interstices of the multifilament core component during the melting period but to also coat the surface of the yarn or thread component. Any excess coating material which may have melted out is trimmed off. While the heating of the covered core mixed yarns can be effected with or

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000163

BUREAU OMPI WIPO

without stretching of the thread in some instances, a better final suture is obtained when the yarn is maintained under tension with little or no stretch applied at this stage. It is at this stage that the basic solid coated core structure is developed.

The impregnated and coated core is then passed through a heated dye which trims coating nubs from the core and otherwise smooths the external surface of the thread. Stretch may also be applied during the smoothing operation, but again, best results are obtained with no or minimum stretch. The thread may be passed through the heating oven or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface coating be removed, but some of it should be used to fill the ups and down of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the coating remaining on the surface follows the contours of the thread and any subsequently applied coating will follow these contours.

The temperatures employed in the heating oven will vary depending on the coating employed, the proportions of coating material to core, the speed at which the core is passed through the oven and whether the heating and/or smoothing is conducted under stretch conditions. As aforementioned, the temperature should be raised above the melting point to a level at which the coating material exudes through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which thin the coating material to a point where it runs off should be avoided as they tend to exude too

BUREAU

much coating material and fail to produce a solid case structure.

Generally speaking, when the impregnation/precoating operation is conducted under stretch conditions, distribution of the coating material throughout the thread and exudation to the surface occurs at lower temperatures than when no stretch is applied. It is important to note, however, that giving the core a high level of stretch in the impregnation/precoating operation reduces or eliminates the ability to apply stretch in the subsequent finish coating stage, in accordance with the preferred embodiment of the invention described below, where it may be used to adjust finished suture properties such as break elongation by additional heat treatment of the highly stretched precoated thread.

The optimum melting temperatures employed in the impregnation/precoating operation will depend primarily upon which suture coating material is employed. The smoothing die temperature will also be above the melting point of the coating material and below the melting point of the core. Usually it will conform closely to the temperature employed in the impregnation/precoating stage preferably about 5 to 15 degrees below that used in the impregnation/precoating stage.

Finish Coating Stage

In the preferred embodiment of the invention, the final stage in obtaining the composite suture structure is to melt extrude coating material onto the smoothed impregnated/precoated thread. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth precoated

thread is simply fed through the extrusion coating die and coated with additional coating material of the same type as used in the impregnation/ precoating stage. As aforementioned, it is important to note that the smooth impregnated/ precoated thread subjected to the coating stage be essentially free of an undulating surface. The extrusion temperatures employed in the impregnation/ precoating stage although it has been found that the higher the extrusion coating temperature, other conditions being equal, the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperature which results in increased polymer flow under a given applied force.

The following examples are included to further illustrate the novel composite sutures of the invention and their preparation. In the examples, reference is made to the following drawings wherein: Fig. 1 is a schematic drawing of an apparatus useful in the impregnation/precoating stage of the present invention; Fig. 2 is a schematic drawing of an apparatus useful in the extrusion coating of the suture impregnated and precoated by use of the apparatus of Fig. 1; and Fig. 3 is a cross-section of the extrusion die in Fig. 2 on a larger scale.

Example I

Directing attention to the drawings, using a conventional New England Butt braider machine 4 strands of "Kevlar", a tradenamed material of DuPont DeNemours, of 30-50 denier having a straight pull tenacity of approximately 7.5 grams per denier are braided around a single core of continuous 40 denier polypropylene having a straight pull tenac-

ity of approximately 4 grams/denier. The raw braid thus formed is wound around a reel 2, and fed through a tensioner 4, about a feed roll (Godet) 6, guide 8 and into a heated 10 cm long tubular oven. The lumen of an extrusion coating die without feed serve this purpose and is designated Heated Zone I in Fig. 1. A draw roll (Godet) 13 pulls the raw braid through the oven without stretch, that is, at a stretch ratio (SR) of 1:1. The Heated Zone I is maintained at a temperature of 230°C. Under these conditions all the polypropylene melts and is entirely distributed througnout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Heated Zone I, large quantities of excess polypropylene which have melted out are trimmed off manually. The braid then continues through a Guide 15 to Heated Zone II which contains a smoothing die 17 having a 0.2 mm diameter that trims and smooths down nubs that are formed on the braid. Heated Zone II is maintained at a temperature of about 220°C for the smoothing operation. The smoothed braid is pulled through Heated Zone II by a draw roll (Godet) 19 and onto receiving reel 21. The speed at which the braid passes through both Heated Zone I and II is approximately 1-1.8 M/min. The precoated braid is passed through the smoothing die 17 three times so as to obtain an impregnated/precoated braid of the desired smoothness.

Referring to Fig. 2, reel 31 of smooth impregnated/precoated braid prepared as above is passed through a tensioner 33, to feed roll (Godet) 35 which feeds the braid through guide 37 into extrusion coating die apparatus indicated generally

as 39. Polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260°C and the melt is forced by means of extruding weights 43 applied at a force of 0.233 kg to a piston 45 into and through the extrusion coating die.

Directing particular attention to Fig. 3, the extruding coating apparatus is comprised of a holder indicated generally as 47 which houses a hollow lumen member 49 a spinneret 57 having an outlet 52. The lumen member 49 essentially positioned within the holder 47 so as to provide an annular chamber 53. A gasket 55 seals one end of the member 49 within the holder while the other end is supported by slotted plate 60. The lumen member contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the spinneret 57 is positioned a hollow needle 63. The impregnated/precoated thread 65 passes consecutively through lumen member 49, hollow needle 59, outlet 52 and is coated with melt as it emerged from the die. The coating die is maintained at a coating temperature of 235°C.

The coated filament is then taken up on draw roll 48 which applies stretch. Tension is let down on draw roll 50 which is run more slowly than draw roll 48. The yarn velocity is 1.43 M/min. and the total stretch ratio (SR) is 1.02. The finished suture is finally wound around receiving reel 51.

The result is a finished composite suture with a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional area and exhibiting a knot break strength of about 3.2 pounds. A knot break strength of 3.2 pounds is equivalent to USP limits of size 2.0 monofilament suture. Thus,

the composite suture prepared can be used as a 5/0, 4/0, or 3/0 suture.

Example II

The process of Example I is repeated substituting a polyethylene terephthalate core for polypropylene core and extrusion coating in extrusion coating die apparatus 39 with polyethylene terephthalate. The result is a composite suture having a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional volume coated with polyethylene terephthalate exhibiting a knot break strength of about 3.5 pounds which is a knot brek strength above the USP limits for a 2/0 size suture. Therefore, the composite suture prepared could be used for sizes 5/0, 4/0, 3/0 and 2/0 according to the physician's wishes.

Example III

Fibroin (silk) is dissolved in a aqueous solution of 62% zinc chloride to give a solution having fibroin weight % concentrations in the range of 5-20%. The resulting solution is maintained at approximately its boiling point and "Kevlar" yarn of Example I is pulled through the solution at a constant rate as to fully impregnate and coat the yarn. The impregnated and coated yarn is then dried by passing it through a tubular oven maintained at heating temperatures up to 130°C. The heat treatment evaporates the solvent and helps to form a continuous fibroin film. The composite suture is then washed with cold water to remove residual zinc chloride.

The resulting composite suture with a size 5/0 "Kevlar" core containing approximately 5% by weight fibroin exhibits a knot break strength of approximately 3.5 pounds which is equivalent to a silk

suture of size 2.0. In other words, the silk-coated "Kevlar" composite suture could be used instead of silk in the following sizes: 5/0, 4/0, 3/0 and 2/0.

Example IV

A size 5/0 high strength fully chain-extended polyethylene multifilament yarn having a straight pull tenacity of 50 grams/denier and a knot tenacity of 15 grams/denier is pulled through a 10% solution of polyethylene terephthalate in a solvent mixture of methylene chloride containing 31% by weight hexafluoroisopropanol and then passed through a die to trim off excess solution. The coated core is dried in air and the process repeated to build up the coating to a final composite suture containing 10% by weight polyethylene terephthalate. The composite is washed with water and dried again. The resulting composite suture could be used for sizes 5/0, 4/0, 3/0, 2/0 and 1/0.

Example V

Example I is repeated substituting a polyglycolic acid (PGA) core for the polypropylene core and PGA resin for the polypropylene chips. The resulting "Kevlar"/polyglycolic acid composite has a minimum knot break strength in the range of 1550-1700 grams. Since commercial non-absorbable "Prolene" sutures of size 3/0 has a knot strength of 1550-1650 grams, this means that a size 3/0 "Kevlar"/polyglycolic acid suture will retain the knot break strength of 3/0 "Prolene" after absorption of all the polyglycolic acid. Thus, the "Kevlar"/polyglycolic acid suture prepared could be used for sized 3/0, 4/0 and 5/0.

When 6/0 size "Kevlar" reinforcing core is used with a non-reinforcing PGA coating, the core by

itself will give a knot strength midway between size 4/0 and 5/0 based on "Prolene" knot strength but above the USP standards for 4/0. Thus, PGA coated "Kevlar" composites with a 6/0 core could be used for size 6/0, 5/0 and possible size 4/0.

With size 7/0 reinforcing core and PGA non-supportive coating 6/0 strength is obtained. Thus, PGA coated, 7/0 core "Kevlar" can be used for sizes 6/0 and 7/0.

Using high strength, extended chain polyethylene having 50 gram/denier straight breaking tenacity, with approximately 1/3 of this converting to knot tenacity, a 5/0 size reinforcing high strength polyethylene core of about 0.140 mm in diameter will impart at least the knot strength of a 2/0 suture to the composite. Thus, a PGA-coated high strength polyethylene 5/0 core can be used to make sizes 2/0, 3/0, 4/0 and 5/0 absorbable, non-absorbable composite sutures.

With high strength polyethylene 6/0 size reinforcing core of about 0.90 mm diameter and a non-supporting PGA coating, the core itself will provide enough knot strength for sizes 4/0, 5/0 and 6/0 based on the knot strength of "Prolene".

With high strength polyethylene 7/0 size reinforcing core of about .060 - .065 mm in diameter and non-reinforcing PGA coating, the core itself will give knot strength sufficient for 5/0, 6/0 and 7/0 composites based on the knot strengths of "Prolene".

With higher strength materials or by increasing the knot strength of the materials mentioned here, a wider spectrum of sizes could be covered with the same fine sized reinforcing core.

In commercial production, needles may be

attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time without a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

Another advantage offered by the composite sutures of the invention is that needles of smaller diameter can be attached thereto. In accordance with this feature of the invention the outside cover or coating of suture material at the end of the composite suture is removed by any suitable means as, for instance, by dissolving the cover using a solvent which solubilizes the cover but not the core. The core at the end of the suture is thereby exposed and onto the core is attached as, for instance, by swagging a needle of smaller outer diamter than would be used with a suture of the same outer diameter. The following example illustrates this feature of applicants' invention:

Example VI

The end of a composite suture prepared according to the general procedure of Example I and having an outer diameter of approximately 0.012 inch is dipped one-eighth inch into boilin xylene until the polypropylene cover softens. The polypropylene cover is then manually scrapped off to expose the 5/0 "Kevlar" core. A 0.014 inch diameter needle is swagged onto the core to provide a suture with a needle having a cross-sectional area reduced approximately two-thirds that of needles required for sutures having a 0.012 inch diameter.

IT IS CLAIMED:

1. A sterile, surgical suture comprising an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams per denier coated with a filmand fiber-forming surgical suture material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

2. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is an aromatic polyamide.

3. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

4. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(1,4-benzamide).

5. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

6. A sterile, surgical suture according to claim 1 wherein the surgical suture material is fibroin.

7. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyester.

8. A sterile, surgical suture according to claim 1 wherein the polyester is polyethylene terephthalate.

9. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyolefin having a straight pull tenacity of about

BUREAU OMPI WIPO INTERNATIONAL

21. A sterile, surgical suture according to claim 2 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided construction.

22. A sterile, surgical suture according to claim 20 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

23. A sterile, surgical suture according to claim 1 wherein the coating of film-forming suture material comprises 5 to 10% by weight of the suture.

24. A sterile, surgical suture according to claim 13 wherein the coating of film-forming suture material comprises 5 to 90% by weight of the suture.

25. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier, with a fiberand film-forming surgical suture material, said coated core when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

26. A method according to claim 25 wherein said coating is effected by solution coating.

27. A method according to claim 25 wherein said coating is effected by melting coating.

28. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers

BUREAU OMPI WIPO INTERNATIONAL

4 to 10 grams/denier.

10. A sterile, surgical suture according to claim 1 wherein the polyolefin is polyehtylene.

11. A sterile, surgical suture according to claim 1 wherein the polyolefin is polypropylene.

12. A sterile, surgical suture according to claim 1 wherein the surgical suture material is collagen.

13. A sterile, surgical suture according to claim 1 wherein the surgical suture material is a film-forming absorbable synthetic polymer.

14. A sterile, surgical suture according to claim 13 wherein the absorbable synthetic polymer is selected from the group consisting of film-forming homopolymers and copolymers of lactide and glycolide.

15. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of glycolide.

16. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of lactide.

17. A sterile, surgical suture according to claim 1 wherein the core is in monofilament construction.

18. A sterile, surgical suture according to claim 2 wherein the core is in monofilament construction.

19. A sterile, surgical suture according to claim 18 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

20. A sterile, surgical suture according to claim 1 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided constructon.

of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, then smoothing said coating.

29. A method according to claim 28 wherein said smoothing is effected by passing said heated thread through a heated smoothing die.

30. A method according to claim 28 wherein the surgical suture material is selected from polyolefin and polyester.

31. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a straight pull tensile strength of at least 18 grams/denier and a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, smoothing said coating and melt extruding similar surgical suture material onto said smoothed coating.

32. A method according to claim 31 wherein the surgical suture material is selected from polyolefin and polyester.

33. A method according to claim 25 wherein the coating is effected by solution coating.

34. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of synthetic polymer having a knot tenacity of at least 7 grams/denier and a lateral strength insufficient to prevent abrasion, fibrillation or kinking on knotting with a film and fiber-forming surgical material in an amount sufficient to increase the lateral strength of said core and provide resistance against said abrasion, fibrillation or kinking on knotting, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

35. A sterile, surgical suture according to claim 1 having a needle attached to said core.

36. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is an aromatic polyamide.

37. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(p-Phenylene terephthalamide).

38. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(1,4-benzamide).

39. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

1/1

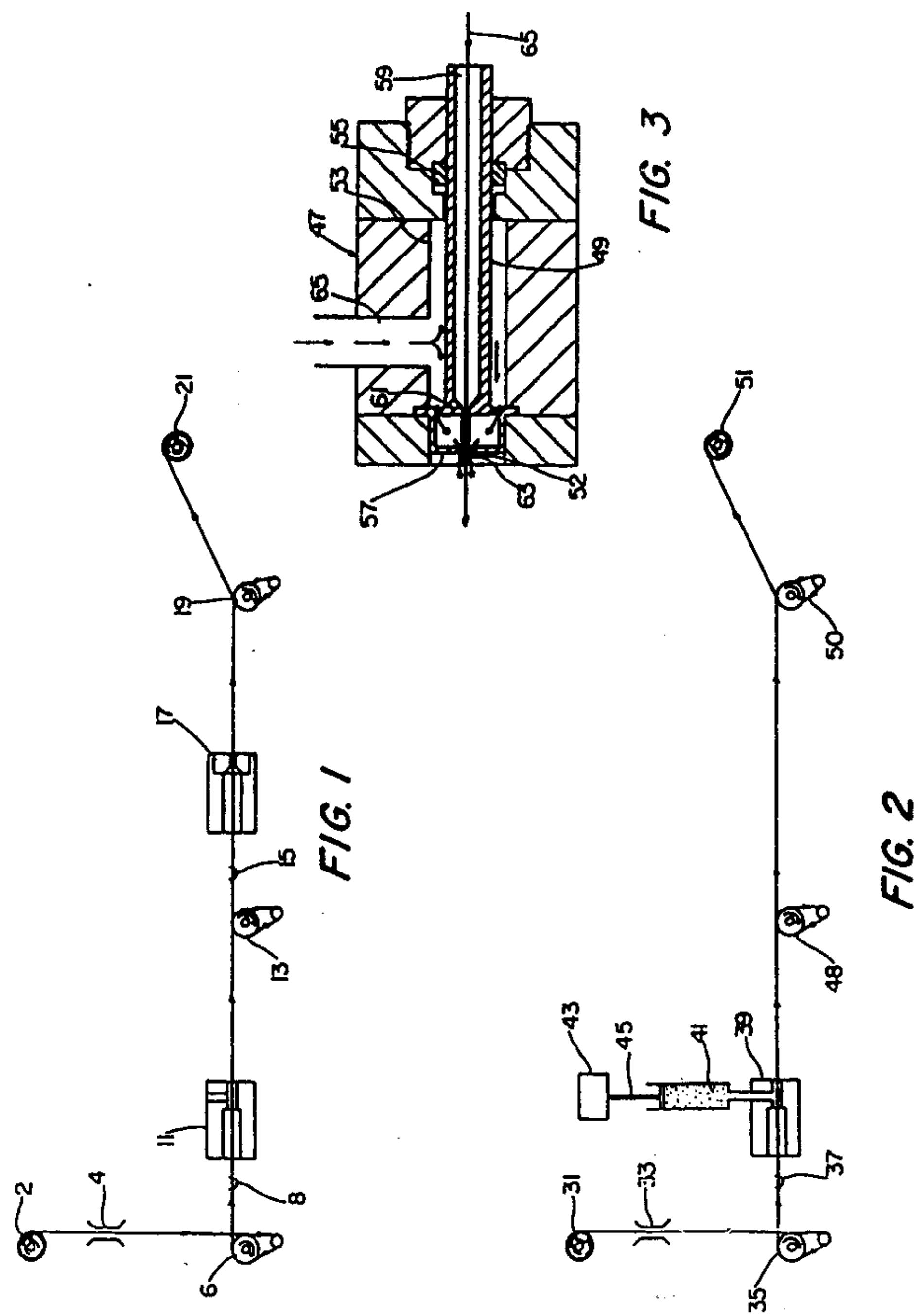


FIG. 3

FIG. 1

FIG. 2

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INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00918

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int Cl [3] A61L 17/00
US CL 128/335.5

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	128/329R, 334R-335.5, Dig. 8, Dig. 18 28/140, 165, 166, 169 66/169R-170, 202 8/Dig. 21 8/490, 529-533, 115.5-115.7, 130.1-132, Dig. 3,

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

cont'd Dig. 9

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X, Y	US, A, 3,791,388 12 February 1974 HUNTER	1, 6-9, 11-17, 20, 23-35
Y	US, A, 4,014,973 29 March 1977 THOMPSON	23, 24, 31
Y	US, A, 3,359,983 26 December 1967 NORTHEY	5, 10, 23, 24, 39
Y	US, A, 3,630,205 28 December 1971 LISTNER	5, 10, 23, 24, 39
X, Y	US, A, 4,204,542 27 May 1980 BOKROS	23, 24, 35-38
X, Y	US, A, 4,336,357 22 June 1982 BARTOLI	23, 24, 35-38

* Special categories of cited documents: [15]
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
31 JULY 1984	17 AUG 1984
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	C. FRED ROSENBAUM

Form PCT/ISA/210 (second sheet) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000180

International Application No PCT/US84/00918

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.☐ Claim numbers , because they relate to subject matter [12] not required to be searched by this Authority, namely:

2.☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-24 and 35-39 are drawn to a surgical suture.

Claims 25-34 are drawn to a method of making a surgical suture.

1.☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2.☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3.☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4.☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (supplemental sheet (2)) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000181

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

______________________________x

DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

READ & SIGN COPY

ARTHREX, INC.,

A Delaware Corporation,

Defendants.

______________________________x

DAY 2 OF 2

CONTINUED VIDEOTAPED DEPOSITION

OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

July 25, 2006

Reported by:

PAMELA HARRISON, RMR, CRR, CSR

Page 333

the last deposition. 12:59:24p
A. Mm-hmm. 12:59:26p
Q. Are you familiar with this document, 12:59:28p sir? 12:59:29p
A. I am. 12:59:29p
Q. What is it? 12:59:30p
A. This is -- well, let me make sure that 12:59:31p -- let me go through it to make sure that... 12:59:34p (Witness reviewing document.) I'm not sure I am 12:59:40p certain as to what that document is. 01:00:05p
Q. Have you seen it before? 01:00:08p
A. I've seen the -- the front page and 01:00:08p the rear page, but I'm -- I don't recall that -- 01:00:11p I don't recall handing counsel the entire 01:00:22p document as such. 01:00:25p
Did I do that? 01:00:27p
Q. This is just what was given to us, so 01:00:28p it's -- 01:00:31p
A. Okay, fine. Okay, fine. 01:00:31p
If this is -- this is material 01:00:33p that I handed to my counsel, that's correct. 01:00:37p
Q. Well, generally what is it? You said 01:00:38p you did know what the first page is, so what is 01:00:41p the first page? 01:00:43p
A. What this is, is some notes that I -- 01:00:44p

Page 334

MR. BONELLA: Object. I think 01:00:46p you just mischaracterized what he said. 01:00:47p
But go ahead. 01:00:49p
THE WITNESS: If your question 01:00:51p is what is this first page, this is a copy of 01:00:53p Dr. Mukherjee's expert report and some notes 01:00:59p that I made regarding it when I initially 01:01:03p received it. 01:01:08p
BY MR. SABER: 01:01:09p
Q. Is the handwritten -- there's some 01:01:09p handwritten materials on this page? 01:01:12p
A. Yes, sir. 01:01:14p
Q. Is that your handwriting? 01:01:14p
A. On the first page, the handwriting, 01:01:18p except for down in the corner, is my handwriting, 01:01:21p yes. 01:01:23p
Q. Down in the corner meaning the 01:01:24p marks -- 01:01:29p
A. The exhibit mark, yes. 01:01:30p
Q. The exhibit mark. 01:01:31p
And when did you make these 01:01:33p notes? 01:01:34p
A. I made these notes -- it's marked 01:01:36p March 6th. Probably March 6th. 01:01:43p
Q. And you think that's -- this was 01:01:47p

Page 335

your -- you made them the first time you reviewed 01:01:49p the report, if I understood your answer 01:01:51p correctly? 01:01:53p
MR. BONELLA: Object to form. 01:01:54p
THE WITNESS: I believe so, but 01:01:55p I'm not certain. 01:02:02p
BY MR. SABER: 01:02:05p
Q. Okay. I want to ask you about near -- 01:02:05p on the bottom there you have numbers one, two, 01:02:09p three, and four? 01:02:11p
A. Yes, sir. 01:02:12p
Q. I want to ask you about number three, 01:02:12p if I could, please. Could you read the first 01:02:14p sentence there, just to make sure that it's -- 01:02:19p
A. This is my note, Mr. Saber, is that 01:02:22p right? 01:02:24p
Q. Yes, sir. 01:02:24p
A. You want me to read my note. 01:02:25p
Q. Yes, sir. The first sentence. 01:02:27p
A. I'll be glad to. 01:02:28p
"'446 -- '446 teachings on 01:02:29p offsetting properties of yarn A with yarn B may 01:02:45p seem to teach away from ultra high molecular -- 01:02:50p UHMWPE, but the critical principle is mixing 01:02:57p yarns and getting better than accepted 01:03:04p

Page 336

properties." 01:03:08p
Q. When you used the -- 01:03:10p
A. I'm not finished. 01:03:12p
Q. Okay. I'm sorry, sir. 01:03:13p
A. It doesn't -- I'm not finished. 01:03:14p
"It doesn't LIMIT," in capital 01:03:18p letters, "A, strength, or B, lubricity, just 01:03:20p suggests it." 01:03:27p
Q. When you used the nomenclature I think 01:03:27p you said UHMWPE? 01:03:32p
A. Yes. 01:03:35p
Q. Does that mean ultra high molecular 01:03:35p weight PE? 01:03:37p
A. That did mean ultra high molecular 01:03:38p weight polyethylene, yes. 01:03:39p
Q. Right. When you wrote at the end, you 01:03:41p said, just suggests it, A, strength, and B, 01:03:46p lubricity, what did you mean by that? 01:03:50p
A. I meant -- I meant specifically that 01:03:51p the teachings in the preferred embodiment in 01:03:54p which -- in which the preferred embodiment 01:03:58p mentions the relationship of -- the preferred 01:04:02p embodiment discussing PTFE, that -- in which we 01:04:05p talk about the strength of the braid and the 01:04:11p relationship of strength to the braid, that that 01:04:17p

Page 337

may seem to be or may mislead others to think 01:04:23p
that that's a description of the entire 01:04:28p
invention, where it is not, where it is limited 01:04:30p
only to the preferred embodiment. 01:04:33p
Q. I want to make sure I understand your 01:04:37p
answer. Could you go back and look at the '446 01:04:40p
patent? 01:04:41p
A. Of course. 01:04:45p
Q. When you talked about just suggests 01:04:57p
it, were you talking about in Column 4, the 01:05:00p
Paragraph 9 through 31 which talks about 01:05:03p
lubricity and then Paragraph 33 through 40 that 01:05:06p
talks about strength -- 01:05:11p
MR. BONELLA: Object to the form. 01:05:12p
BY MR. SABER: 01:05:13p
Q. -- in the most preferred embodiments 01:05:13p
that you were talking about? 01:05:15p
MR. BONELLA: Object to form. 01:05:17p
Mischaracterizes testimony. 01:05:18p
THE WITNESS: No, I was speaking 01:05:46p
in terms of the most preferred embodiment 01:05:47p
starting on Page 41 -- starting on Line 41 -- 01:05:52p
please correct that -- Line 41 of Column 4. 01:05:59p
BY MR. SABER: 01:06:07p
Q. That's what you think that note 01:06:07p

Page 338

referred to, and not to the paragraphs above? 01:06:09p
MR. BONELLA: Objection. Asked 01:06:11p
and answered. 01:06:12p
BY MR. SABER: 01:06:13p
Q. Is that right? 01:06:13p
A. Yes, that's correct. 01:06:14p
Q. You don't say PTFE and PET in your 01:06:17p
note, do you, sir? 01:06:21p
A. No, I don't say PTFE in my note. 01:06:28p
Q. Or PET? 01:06:31p
A. No, I don't. 01:06:32p
Q. You'd say strength and lubricity, 01:06:33p
correct? Is that correct? 01:06:40p
A. I say that it doesn't LIMIT, in 01:06:42p
capitals, strength and lubricity. 01:06:45p
Q. Now, earlier on in that note you say, 01:06:49p
may seem to teach away from ultra high molecular 01:06:51p
weight PE. 01:06:54p
Do you see that, sir? 01:06:57p
A. Yes. 01:06:57p
Q. What did you mean by that? 01:06:58p
A. I meant that the comments in Line 41 01:07:01p
could be -- could be misinterpreted as being 01:07:04p
expanded to the entire set of yarns that appear 01:07:07p
in section -- in the list A in the patent, just 01:07:11p

Page 339

as you've done. 01:07:19p
Q. Well, the beginning part of your note 01:07:22p
says '246 teachings -- '446 teachings are 01:07:24p
offsetting properties of yarn A with yarn B, 01:07:30p
correct? 01:07:31p
A. That's what the note says, yes. 01:07:33p
Q. Is it your testimony that you're only 01:07:34p
referring to one embodiment by that note? 01:07:36p
A. Yes, it is. 01:07:39p
Q. You weren't talking generally about 01:07:40p
the patent? 01:07:41p
A. No, I was talking about that 01:07:42p
embodiment. 01:07:44p
Q. When you say, critical principle is 01:07:46p
mixing yarns and getting better than accepted 01:07:52p
properties, you were only talking about one 01:07:54p
embodiment; is that your testimony? 01:07:56p
MR. BONELLA: I object to form. 01:07:59p
It mischaracterized what he just said. 01:08:00p
THE WITNESS: I was speaking of 01:08:17p
the whole patent there. 01:08:18p
BY MR. SABER: 01:08:19p
Q. Okay. Well, is just the back part of 01:08:19p
the sentence talking about the whole patent, or 01:08:22p
the whole sentence talking about the whole 01:08:24p

Page 340

patent? 01:08:26p
MR. BONELLA: Objection. Asked 01:08:27p
and answered. 01:08:28p
THE WITNESS: The back part of 01:08:34p
the sentence is talking about the whole patent. 01:08:35p
BY MR. SABER: 01:08:36p
Q. I just want to make sure I understand 01:08:36p
your testimony. The first part of the patent, 01:08:38p
'446 teachings are offsetting properties of yarn 01:08:41p
A with yarn B may seem to teach away from ultra 01:08:45p
high molecular weight PE, refers only to Column 01:08:50p
4, Lines 41 to 59 -- 01:08:54p
MR. BONELLA: Objection. Asked 01:08:59p
and answered. He already -- 01:08:59p
BY MR. SABER: 01:09:00p
Q. -- but the rest of the sentence refers 01:09:00p
to the patent in its entirety? 01:09:02p
MR. BONELLA: Objection. Asked 01:09:04p
and answered three times. 01:09:04p
BY MR. SABER: 01:09:05p
Q. Is that your testimony, sir? 01:09:05p
A. It's important to note that the note 01:09:11p
reads '446 teachings on offsetting properties, 01:09:14p
not -- that is my testimony -- 01:09:18p
Q. Okay. 01:09:21p

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-o-

DEPUY MITEK, INC., a Massachusetts Corporation,	:	Civil Action No. 04-12457 PBS
Plaintiff,	:	
-vs-	:	
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LTD., a Private Limited Company of the United Kingdom,	:	EXPERT DEPOSITION OF:
	:	ROBERT T. BURKS, M.D.
Defendants.	:	

-o-

Location: Mariott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

-o-

6

court reporter can transcribe them as opposed to shaking your head or nodding your head; do you understand that?
A. Yes.
Q. Also, if you'll allow me to finish the question before you answer, it will make for a better transcript. Even though you may even be able to anticipate the end of my question by what I say in the beginning, if you'd allow me to finish and then answer it will allow the reporter to make a clear transcript; do you understand that?
A. I do.
Q. Also, if I ask you a question and you don't understand, I'll ask that you tell me you don't understand the question. Otherwise, I'll assume that you did understand the question; is that fair?
A. Fair.
Q. Are you being represented today by counsel?
A. Yes.
Q. Who is your counsel?
A. Sal Tamburo.
Q. Do you know when Sal or the law firm Dickstein Shapiro Morin & Oshinsky began representing you for purposes of this case?

7

A. In February.
Q. Is that when Arthrex or Dickstein contacted you with respect to your role in this case?
A. Yes.
Q. Are you being compensated for the time you spend on this lawsuit?
A. Yes.
Q. How are you being compensated?
A. How much?
Q. Yes.
A. $400 an hour.
Q. Was that a negotiated fee or was that your standard fee for doing expert consulting?
A. I don't really have a standard fee, so I guess you could call it negotiated.
Q. Other than money, is there any other compensation you are receiving for work on this case?
A. No.
Q. Were you given any dollar amount that you should not exceed in performing work for Arthrex in this case?
A. No.
Q. I'm going to hand you DePuy Mitek Exhibit 231 and ask you if you recognize this document, Exhibit 231?

8

A. Yes.
Q. What is Exhibit Number 231?
A. A subpoena for me.
Q. Did you understand that be Exhibit 231 was a subpoena on you for certain documents and things listed in schedule A of Exhibit 231?
A. Yes.
Q. Today are you producing any documents or things in response to the subpoena, Exhibit 231?
A. No.
Q. If you could turn to page two of Exhibit Number 231, please. Do you see request number one for documents there, being all communications between any of Arthrex, you, Dr. Mukherjee and Dickstein Shapiro Morin & Oshinsky concerning the lawsuit commenced by the plaintiff attached as Exhibit 1?
A. Yes.
Q. Did you perform any search that might be responsive to request number one in Exhibit Number 231?
A. Yes.
Q. Did you find any?
A. No.
Q. Request number two in Exhibit 231 is all documents concerning this lawsuit, including, but not

9

limited -- well, hold on. Strike that.
Did you perform a reasonable search for documents in response to request number two in Schedule A of Exhibit 231?
A. I guess I don't see the difference. There aren't any documents that I'm aware of in the lawsuit.
Q. Under things to be produced on page two of Exhibit Number 231, request number one is all tested and untested samples referred to in Expert Report of Robert T. Burks, MD dated March 24, 2006, including, but not limited to suture A and suture B. Do you see that?
A. I do.
Q. Did you perform a search for things responsive to request number one?
A. No.
Q. You did not?
A. I knew it didn't exist.
Q. You knew what didn't exist?
A. The suture.
Q. You mean the tested and untested samples?
A. The pieces that I had I had disposed of when I was done. I knew there wasn't anything to look for.
Q. Under request number two on things to be

10

produced on page two of Exhibit 231 is all equipment used to test the samples as described in paragraphs nine through 13 of Expert Report of Robert T. Burks, MD dated March 24, 2006, including, but not limited to the equipment that was used to cut and wet the samples and to conduct the tactile feel analysis and knot tie-down analysis; do you see that?
A. I do.
Q. Did you perform a search for the materials requested in request number 2?
A. No.
Q. Why not?
A. The equipment that was used was a pair of scissors just to cut it, something from home, I felt like it didn't have relevance.
Q. What about the solution that was used to wet these tested samples?
A. I used tap water.
Q. Did you use anything else in performing the tests described in paragraphs nine through 13 of your expert report other than tap water and scissors and the sutures?
MR. TAMBURO: It might help if the witness had his report in front of him to refer to.
A. The things used, like a pair of gloves,

11

are disposed of after and they're just a generic set. There wasn't anything used that would be unique that I felt would be worthwhile to produce.
Q. So you used gloves when you performed the tactile feel analysis and knot tie-down analysis?
A. I did both. I used and didn't use gloves.
Q. Is there any reason why you decided not to bring gloves today?
A. No.
Q. Did your counsel advise you to bring gloves?
A. No.
Q. Did you go over -- did you have a chance to go over Exhibit 231 with your counsel before coming to today's deposition?
A. Yes, we looked at it.
Q. Dr. Burks, could you please describe your formal education post-high school for me, please.
A. I did medical school at St. Louis university. I guess after high school I did college at Southern Methodist University, medical school at St. Louis university, orthopedic training at University of California San Diego.
Q. When did you graduate from undergrad?
A. Undergrad college was '74.

12

Q. What about medical school?
A. '78.
Q. Then, after medical school, where did you go?
A. To residency training.
Q. When did you finish your residency training?
A. '83.
Q. Where was your residency training?
A. University of California San Diego.
Q. Did you have a specialty there?
A. Yes. Well, there's no specialty in training per se, but I did do a fellowship during that time with Dale Daniel at Kaiser Permanente.
Q. What was that fellowship in?
A. Knee and sports medicine.
Q. When did you finish your fellowship in knee and sports medicine?
A. '83.
Q. Other than those programs or degrees you mentioned, are there any other -- is there any other formal education that you've gone through?
A. No.
Q. Once you completed your fellowship in knee and sports medicine in 1983, what did you do?

13

A. I went into private practice in St. Louis, Missouri.
Q. What was the focus of your private practice in St. Louis?
A. Sports medicine, general orthopedics.
Q. Did you focus on any particular parts of the body within sports medicine and general orthopedics?
A. Knee and shoulder were the big focus.
Q. And when did you leave private practice in St. Louis?
A. I was there three years; I believe it was '86.
Q. Then what did you do in 1986?
A. I went to Wayne State University in Detroit.
Q. What did you do at Wayne State?
A. I was on the academic staff there and was the head of sports medicine.
Q. Your time spent at Wayne State, was that strictly in an academic environment or did that also include a clinical practice?
A. Yes. I mean, it was a clinical practice, but it was as a full-time faculty member.
Q. Can you explain how that works, your role

at Wayne State, how it was spent between full-time faculty member and participating in a clinical practice?
A. Well, there's really no distinction. I mean, my job was to take care of patients and people. And so the education was for residents and that's what they were training to do was take care of people.
So there really wasn't a distinction between a clinical practice and what you are doing academically as far as your work goes.
Q. So did you teach in a classroom setting?
A. No.
Q. So I think I understand. What type of medicine did you practice at Wayne State as a full-time faculty member and in a clinical practice?
A. It was orthopedic surgery with an emphasis in sports medicine.
Q. Again, did you focus on the knee and shoulder areas?
A. Yes.
Q. When you were at Wayne State what were the -- generally what were the procedures that you would perform for shoulder surgeries?
A. Perform shoulder instability operations, rotator cuff operations, things that we do for what we

call impingement, shoulder pain procedures, procedures that revolve around the clavicle.
Q. Anything else you can think of?
A. I mean, it's a pretty wide area, but those are the main things.
Q. What about when you were at Wayne State, what were the procedures that you would perform for knee surgeries?
A. Ligament reconstructions, operations for instability of the knee cap, cartilage procedures, meniscus procedures.
Q. When you were at Wayne State, did you perform any ankle surgeries?
A. Sure.
Q. What ankle surgeries? What procedures would you perform doing ankle surgeries?
A. The main procedures revolved around arthroscopy, and then I would do some procedures that revolved around loose ankle joints where people have chronic ankle sprains and tightening those up.
Q. Then, I take it, at some point you left Wayne State?
A. Correct.
Q. What year was that?
A. '88.

Q. In 1988 after leaving Wayne State, what did you do?
A. I came here to the University of Utah.
Q. What position did you enter the University of Utah in 1988?
A. I was an assistant professor in orthopedic surgery. And we didn't really have a true division, but I was part of the sports medicine team.
Q. Can you generally describe your duties as an assistant professor in the orthopedic surgery department at the University of Utah?
A. Duties were to take care of standard patients that we would see, to instruct residents in clinical evaluation of patients and surgical treatment of patients, to be involved in some areas of research and produce academically, and were involved with taking care of the athletic teams.
Q. While at the University of Utah, I take it from 1988 to the present you've remained at the University of Utah?
A. Yes.
Q. From 1988 to the present, do you perform any classroom teaching?
A. Minimally. Occasionally it comes up, but not very much.

Q. What classes would you teach when it comes up?
A. It's usually just an isolated lecture, not like a class series. So it would be lectures to the residents or to medical students on a specific topic, sometimes to physical therapy students.
Q. Since 1988, how have your duties and responsibilities at the University of Utah changed?
A. I don't think they've changed much.
Q. Okay. At some point you did become head of the sports medicine division, though, right?
A. Correct.
Q. Do you know when that happened?
A. I'd be guessing a little. I'm not sure of the exact year.
Q. How about 1992, does that sound familiar?
A. That's probably close.
Q. Dr. Burks, I'm going to hand you Exhibit Number 233. This is a printout of a web page from the University of Utah. If you could just please look at that.
MR. TAMBURO: Do you have another copy?
Q. No. Just let me know if that's generally accurate.
A. Yes.

18

Q. Dr. Burks, can you describe for me your relationship with Arthrex, Inc.?
MR. TAMBURO: Objection, vague.
A. I am a consumer. Over the years I have been an advisor for different products. That's it.
Q. You say you are a consumer of Arthrex products. What Arthrex products do you use?
A. Well, we use things like drill guides, use suture anchors and sutures, drill bits. That's it.
Q. Do you use any Arthrex knee fixation devices?
A. I have used Arthrex knee fixation devices but don't currently use any.
Q. What did you use?
A. They have an interference screw that is metal and one that is absorbable that I used to use that I don't use now.
Q. Earlier you said things like we used things like drill guides, suture anchors, and sutures, drill bits. Who were you referring to when you said "we"?
A. I guess it was the generic "we" of the sports medicine service.
Q. Do you personally use those Arthrex products?

19

A. Oh, yes.
Q. Do you have any consulting agreements with Arthrex?
A. To be honest, I'm not sure of the direct answer to give you on that. I have a couple of pieces of equipment that I have worked with them on in developing, so that might be considered a consulting agreement.
I'm not a consultant, just a generic like on a board of advisors or something like that.
Q. I don't understand when you say "I have a couple of pieces I equipment I worked with them on in developing so that might be considered a consulting agreement", could you explain that?
A. Well, I went to them to develop a guide for a knee ligament reconstruction. They liked the idea. They made the guide. They have the guide as one of the products that they sell, and then I get some royalty from their sales.
Q. Okay. So other than services you performed for this case, have you received money from Arthrex for other services such as, for example, this work you did with the guide?
A. I think I just said I get royalties for that.

20

Q. Other than royalties and other than money for your work you've performed in this lawsuit, do you receive any other money from Arthrex?
A. No.
Q. How many different pieces of Arthrex equipment to you receive royalties on?
A. There is a knee ligament guide system that has a few different pieces in it. So I can't give an exact number. It's sort of a guide system with four or five different pieces, parts of it.
There is a screw that we use for augmenting ligament fixation that I get some royalties on along with those guides.
Q. Do you know what the trade name is for the knee ligament guides that you receive royalties from Arthrex on?
A. It's kind of silly that I wouldn't be able to give you that. It's for posterior cruciate ligament reconstruction.
Q. And do you know what the trade name is on the screw that you receive royalties from Arthrex on?
A. I don't.
Q. For what area of the body is this screw used on?
A. It could be used anywhere, but I think the

21

large majority would be at the knee.
Q. Are you the named inventor on any patents?
A. No.
Q. The screw that you developed with Arthrex, is that used for the ACL or PCL?
A. Can be either.
Q. Is that an interference screw?
A. No. It's a screw we typically refer to as a post. And what that means is that suture from a ligament or tendon gets tied around this to help hold it while it's healing in.
Q. You also said, in describing your relationship with Arthrex, you used the word "advisor". We've just been talking about you developing certain equipment. Is that what you meant by advisor?
A. Yes.
Q. Do you advise Arthrex in any other way other than what we've just talked about with respect to developing equipment?
A. No.
Q. Do you know Dr. Paul Fenton from Toledo, Ohio?
A. I don't.
Q. What about Dr. Marlow Goebel?

50

A. Poor wording. I guess it was to say that my sense of how FiberWire works and handles, that subjective feel of that is in that environment.
Q. So you don't use FiberWire in any non-surgical environment, do you?
A. Well, I've used FiberWire in laboratory studies when we do cadaveric studies or other things. But I don't use it for non-medically related things.
Q. When you say "most of my subjective use of FiberWire occurs during surgery", were you referring to the surgical environment versus non-surgical environment like you just described?
A. Right.
Q. Then you say "FiberWire is generally wet in the surgical environment", what does that mean?
A. Well, in the environment where I work arthroscopically we work with fluids, so it's hard for a suture not to be wet.
Obviously, there are times where we work in a dry air environment and the suture may get wet passing through tissue, but it's not necessarily intentionally wetted like it is with arthroscopy.
Q. During surgery, do you wet FiberWire before is it's introduced into the body?
A. Not deliberately, no.

51

Q. Earlier you said the suture may get wet passing through tissue, but it's not necessarily intentionally like it is with arthroscopy. I don't know what that means.
A. In an arthroscopic environment we have a microscope in a joint and we distend the joint so we can see with fluid.
So any time we introduce suture into that environment it's under water, if you will. So no matter what we do with it, by the time we start to use it, it's wet.
Q. When using FiberWire in a surgical environment, do you always wear gloves?
A. Yes.
Q. What about in the -- let me rephrase the question. In a nonsurgical environment, do you always wear gloves when using FiberWire?
A. No.
Q. What determines whether you wear gloves?
A. Either sterility for a patient or protection for myself.
Q. If it's a nonsurgical environment, how does sterility of the patient matter?
A. It doesn't.
Q. In a nonsurgical environment, what

52

determines whether you wear gloves?
A. In a nonsurgical environment it would be protection for me.
Q. Okay. Protection from what?
A. Well, if we do cadaveric surgery some cadavers have diseases so we may want to have gloves on when we work with them.
Q. What about in the laboratory environment, when you are using FiberWire, do you wear gloves?
A. I guess it depends on what you mean by the laboratory environment.
Q. By laboratory environment, I mean anything other than a surgical or nonsurgical environment like we've been talking about.
A. Well, we do, for example, cadaveric surgery in the laboratory, so we would consider that a laboratory environment, and I would use gloves for self-protection in that setting.
Q. Let me ask you a better question. Outside of a surgical environment or nonsurgical environment, do you wear gloves when using FiberWire?
A. I guess I would say no.
Q. Dr. Burks, if you could turn in Exhibit 232 to paragraph eight, you state: "Sometime in February 2006 I was contacted by attorneys for

53

Arthrex, Inc., and asked to conduct a tactile feel analysis as well as a knot tie-down analysis of coated and uncoated FiberWire suture. I agreed to conduct the analysis." Do you see that?
A. I do.
Q. Who contacted you in February of 2006?
A. Sal Tamburo.
Q. Anyone else?
A. No.
Q. Do you remember the substance of the conversation you had with Sal in February of 2006?
A. Yes.
Q. What was that substance?
A. He said that Arthrex and more, in particular, FiberWire was involved in a patent infringement lawsuit and he was wondering, since I've had experience of using FiberWire, if I would be willing to talk about FiberWire and how its used, etc., and if I'd be willing to look at FiberWire in a couple of different states and give him feedback on what I thought about that.
Q. What were those couple different states?
A. My understanding was that it was a coated suture and a not-coated suture.
Q. Anything else?

70

A. I'll try to clarify again. I didn't, in my mind, view it as a pure test A/test B. So when you handle suture tying knots and doing things with it, you have a tactile feel. So I didn't -- so that's part of the knot tying. So I didn't segregate it out as two isolated separate things.
Q. So in your report, Exhibit 232, are you making two conclusions based on a conclusion of the tactile feel analysis and a conclusion based on the knot tie-down analysis?
A. I'll try to clarify again. A knot tie-down analysis I view as having a tactile aspect to it as well, you are feeling the suture as you tie it. So I don't view them as totally isolated.
Q. Okay. So how many analyses did you perform as reflected in Exhibit 232?
A. I used all the strands and tied multiple knots on all the strands. So I'm not, I guess, quite sure -- I can't tell you I did 20 knots on each strand or 30, but they were each used for multiple knot tying.
Q. My question might have been unclear. Not how many times did you perform the analysis, but how many different analyses did you do in coming to the conclusions as expressed in Exhibit Number 232?

71

MR. TAMBURO: Objection, vague.
A. I felt the suture and I tied knots with the suture.
Q. But earlier you testified that that's all encompassed in the knot tie-down analysis. So I'm wondering did you do a knot tie-down analysis and that's it and that had two subparts or two different analyses and then come up with a conclusion -- come up with two different conclusions?
MR. TAMBURO: Objection, mischaracterizes the testimony.
A. Again, I'm not trying to characterize in this that these are segregated separate tests, but this was a tactile feel and knot tying. It was a length subjective feel on both of those.
So when you tie knots, you get a tactile feel. So I was making the statement that on the tactile feel, how it feels to me, it felt this way and when I tied knots, it also felt that way. It's sometimes hard to do one without doing the other.
Q. When you were doing -- when you did the tactile feel analysis and the knot tie-down analysis as expressed in Exhibit 232 were you wearing gloves?
A. Not always.
Q. Can you explain the breakdown?

72

A. I tried to try knots partly with gloves to see if I felt that there was a difference and partly without gloves to see if I could feel a difference.
Q. Did using gloves in the tests in Exhibit 232 affect your ability to distinguish between suture A and suture B?
A. I think, clearly, using gloves makes the feel of the suture a little different. I guess I can't answer directly to say if it makes the difference but, yes, it probably makes a difference.
Q. What difference does it make?
A. You are covering your skin with the gloves, so, you know, as you feel suture, your absolute sensation of the suture probably changes some.
Q. Could you have reached the same conclusions you reached in Exhibit 232 if you solely used gloves in performing the tests?
A. I didn't do it that way, so I guess I can't answer that and say yes or no.
Q. Did not using gloves help you to distinguish between suture A and suture B?
A. Potentially, yes.
Q. Did it or -- I'm asking you if, in fact, it did?

73

A. And I'm telling you my answer is it potentially did.
Q. I don't think I understand that. How could it potentially? I mean either it did or didn't, right?
A. No.
MR. TAMBURO: Objection, argumentative.
Q. Why do you say "potentially"?
A. I'm trying to be honest. I did feel without gloves and I know there's a pile A and a pile B, so there is potential that feeling suture without gloves made me feel that A was a little different than B that had I been gloved the entire time, I might not have detected.
Q. So from start to finish then after you cut the suture samples until the time you made your conclusions expressed in Exhibit Number 232, how long was that?
A. I'll give you the same answer: 45 minutes or so.
Q. So the 45 minutes encompassed roughly ten minutes you spent on the tactile feel analysis?
A. No.
Q. So 45 minutes plus ten minutes or just 45 minutes?

it was my overall take from looking at them.
Q. Do you remember how many -- strike that. Does a suture that has less friction when sliding that knot mean that the suture has better knot tie-down performance?
A. Not necessarily.
Q. Why?
A. Well, if you envision a perfectly smooth suture, for example, if you slide a knot it might slide very easily but it might also tend to not hold as well because there's not as much inherent friction in it.
Q. Does a smoother suture mean it has better tactile feel than a suture that is not as smooth?
A. I would say no, I don't know that I'd say it's a better tactile feel.
Q. Why did you use a surgeon's knot when you did the knot tie-down analysis in Exhibit 232?
A. I think what I would do is say that -- again, maybe my critique of the verbiage would be at fault. So I guess I wouldn't -- you know, we talked earlier about what a surgeon's knot is.
Q. Uh-huh?
A. And I probably didn't focus on it enough to say that they're not necessarily surgeons' knots as

I described them.
Q. Okay, so why did you use the particular knots, then, that you used in the knot tie-down analysis?
A. I just tried to reproduce what I do in the operating room.
Q. In paragraph 11 in Exhibit 232 you state that suture A generally felt smoother than suture B. What do you mean by "generally"?
A. The differences between the sutures were subtle. I mean, they were not sharp, distinct. So I'm meaning that in comparing them, my take was that it was generally smoother.
Q. Were there any of the sutures in the tactile feel analysis where you couldn't tell the difference between suture A and suture B?
A. It was not my intent at the time in looking at the sutures to compare each strand side to side. My intent was to look at sort of spool A and spool B. So it was to get a feel of, in general, how do they feel between the two.
So I didn't take a strand and say is this one different? And is this one different? And go down through that five times, because I felt it was all the same suture.

Q. But were there any where you couldn't tell a difference? I mean, it was pretty close?
A. Sure, it was pretty close.
Q. Let me rephrase. Were there any where you couldn't tell the difference between suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. I don't remember specifically having ones that I would say I clearly feel a difference on this one and I clearly don't on the next one. It was a general feel of all of them.
Q. Dr. Burks, how would you describe your relationship with Ethicon?
A. I guess none.
Q. None? So you would say that you have a closer relationship with Arthrex?
A. Yes.
Q. What about could you describe your relationship with DePuy Mitek?
A. I have been a consultant with DePuy Mitek. Just this week I was helping on an educational course for DePuy Mitek reps. But I've had no product or anything like that with DePuy Mitek.
Q. You mean development product work?

A. Yes.
Q. What was the educational course this last week that you helped with DePuy Mitek?
A. It was educating reps who go into the operating room and, you know, are helping surgeons with their materials, sutures, implants, what not, and how to handle the operating room environment, be appropriate and be helpful.
Q. The course was not on a particular DePuy Mitek technique or anything like that, it was --
A. It was not focused on a particular product but it was focused on helping reps better sell DePuy Mitek products.
Q. By being more professional in the operating room?
A. Correct.
Q. Is this the first time you have done that for DePuy Mitek?
A. This is the second.
Q. Other than those two courses, have you consulted with DePuy Mitek in any other courses?
A. Yes.
Q. What are those?
A. There was an educational course in Chicago and you are going to say when and I'm going to guess

four years ago. It was a cadaver course where they were doing DePuy Mitek products and they asked me to come give a couple of talks and help in the lab using those products with the doctors who were there.

Q. Do you remember what those products were?

A. Not specifically. They were suture anchors, suture passing instruments, but I don't remember a specific product.

Q. Are you a consumer of DePuy Mitek products?

A. Sure.

Q. What DePuy Mitek products do you use?

A. Well, I mentioned earlier I use OrthoCord. I use some DePuy Mitek anchors. They make an electric cautery unit that we use, in every case we use electric cautery.

They have some suture-passing instruments that we use. I use one of their drill guides and fixation sets for ACL surgery.

Q. When you do an ACL fixation, what product do you use?

A. It depends on the type of ACL that we're doing. If I use a bone/tendon/bone graft which is a common graft, on the femoral side, I fix it with a DePuy Mitek device which is a couple of absorbable

pins, and on the tibial side I fix it with either a DePuy Mitek screw or a screw from a different company depending on upon quality.

On the hamstring, I typically on the femoral side use a Smith and Nephew product --

Q. EndoButton?

A. EndoButton. On the tibial side I typically use a Milagro screw and frequently for the post use that Arthrex screw.

Q. When you say hamstring, that's soft tissue?

A. Correct.

Q. Semitendonosis?

A. Very good.

MR. TAMBURO: We're all half doctors here.

MR. FALKE: Let's take a break.

THE VIDEOGRAPHER: Off the record, 5:54.

(Brief recess.)

THE VIDEOGRAPHER: On the record, 6:02.

Q. (By Mr. Falke) Dr. Burks, I'm going to hand you DePuy Mitek Exhibit 286, DePuy Mitek Exhibit 284 and DePuy Mitek 285. These are FiberWire samples that were produced to us from Pearsalls who is a company that makes FiberWire for Arthrex.

I covered up on those exhibits the

manufacturing state that those sutures have gone through. And I'm wondering if you can look at those, analyze them, do whatever you have to do, but tell me which ones are coated and which ones are not coated, if any?

A. So these are three separate types of suture?

Q. They're three different sutures. Well, I'm going to take that back. I don't know if they're three different sutures.

MR. TAMBURO: You are not sure what they are.

MR. FALKE: We know what they are, yeah. I mean, based on Pearsalls' representations of what they are. If you need to cut them and get you a glass of water, if you want to wet them.

MR. TAMBURO: Are they in the same form in which they were produced?

MR. FALKE: Yes, we did not alter them.

MR. TAMBURO: Do we have Bates numbers?

Q. Slow down. Just for the record, so the record is clear, what did you just do, Dr. Burks?

A. I just opened the suture that was in the bag.

Q. What Exhibit Number is that?

A. That is 286.

Q. You cut a piece off of the suture in Exhibit 286?

A. Right.

Q. And --

MR. TAMBURO: There's no Bates numbers on these?

MR. FALKE: There were no Bates numbers.

Q. Would you put that on the suture you cut from Exhibit 286 and mark with a pen Exhibit 286. Now, can you explain what you are doing now, Dr. Burks? First, can you put the suture that you took out of 286 back in the bag?

A. (Witness complies.)

Q. Thank you, and then proceed. Can you explain for the record what you are doing now?

A. I'm opening 285.

Q. You are cutting suture sample from Exhibit 285, right?

A. Yes.

Q. Could you please mark with the tape Exhibit 285 that you've cut? Proceed. Can you state what for the record what you are doing now?

A. I'm opening number 284.

Q. And cutting a suture from Exhibit 284?

94

A. Yes.
Q. And now you are going to mark the suture sample that you took from Exhibit 284 with a flag?
A. Correct.
Q. Can you hand me the original sample sets back?
A. (Witness complies.)
Q. Also, I'm going to hand you DePuy Mitek Exhibit 234 which is a chart I'd like you to fill out if you could, please, and under the suture column put the numbers corresponding to the suture samples you've just cut, just 284, 285 and 286?
A. Fair enough?
Q. Fair enough.
A. Have we got a while?
Q. However long it takes you.
MR. TAMBURO: Are you representing that one of them is coated, one of them is not coated?
MR. FALKE: I'm not making any representations. They could all be coated, they could all be uncoated, could be a mix?
A. Can I use your notebook?
Q. Of course. What do you need?
A. I was going to use one of those metal rings.

95

Q. Sure. First, can you do a tactile feel analysis on it? Can you tell the difference?
A. Kind of -- like I said, when you tie knots you combine that together.
Q. Can you explain what you are doing now?
A. I don't want to knock your little deal off, you know? I'm just getting a sense for how it slides and trying to put down a couple of throws.
Q. Which Exhibit Number are you working on?
A. I'm on 285.
Q. Okay. What type of knots are you throwing?
A. Half hitches.
Q. Now, can you explain what you are doing, Dr. Burks?
A. Same thing.
Q. With which exhibit?
A. 286.
Q. Are you doing the same thing you did with the previous one?
A. Yes.
Q. Same knot configurations?
A. Uh-huh.
Q. Can you tell a difference between the first two sutures, Dr. Burks, Exhibit 285 and --
A. 286.

96

Q. And 286? Can you explain for the record please what you are doing now, Dr. Burks?
A. I'm tying 284.
(Discussion off the record.)
A. Okay. So where is my little sheet here?
Q. Based on what you've done so far, Dr. Burks, can you tell any difference between the sutures?
A. I feel like I do feel a difference.
Q. Okay. How would you describe that difference?
A. Well, I would say at the moment 285 seems a little smoother to me than 284. So I would say 285 is coated and 284 isn't coated.
Q. How sure are you of that?
A. I would not put my children's lives on it, but given the subjective feel.
Q. Is it a subtle difference?
A. It's a subtle difference.
Q. Can you explain, Dr. Burks, what you are doing now?
A. Just throwing knots. I would say 286 seems coated as well.
Q. If you had gloves on right now, would that change the confidence level you have in determining

97

whether those are coated or uncoated sutures?
MR. TAMBURO: Objection, calls for speculation.
A. I think gloves can make a difference, yeah.
Q. How do they make a difference? The difference between the sutures is more subtle, right, with gloves because you don't have the contact like you described earlier with the skin?
A. Yeah. Again, this is obviously a very subjective feel test. Some of that feel comes from how the suture feels and some of it comes from how you feel when you slide a knot. So we're not talking rocks and water as far as differences and so. . .
Q. How would you qualify the difference that you just observed, based on your test?
A. When you say "qualify" are you asking for like an amount?
Q. How would you characterize the difference between the sutures?
A. Well the difference is, I think, subtle and there's no doubt in my mind that I could line up, you know, a hundred sutures and have error where I would say, you know, I think this one is one way or the other and make a mistake.

So there's certainly not enough difference to clearly say that I know every time exactly how that feels.

Q. Okay. Could you just initial, please, the chart that you did?

A. This right here?

Q. Yes.

A. Okay.

Q. And put the date.

A. (Witness complies.)

Q. Okay. For the record, I have to mark the exhibits, the sutures that you tied onto my binder. Can you untie those?

A. I can just open the binder.

Q. How confident were you that 286 was coated?

MR. TAMBURO: Objection, vague.

A. I guess I've said that differences are subtle. So I'm going by a subjective feel. So I feel like there's a difference. Am I going to bet a lot of money on it? No, but that's my take.

MR. FALKE: Okay. For the record I'm going to mark the suture that Dr. Burks tested with Exhibit 235 -- I'm going to state that over again.

For the record, I'm going to mark with

Exhibit 235 the suture Exhibit 284 that Dr. Burks just tested, and I'm going to mark Dr. Burks' tested suture 286 with DePuy Mitek Exhibit 236, and I'm going to mark Dr. Burks' tested suture 285 with DePuy Mitek Exhibit 237.

I have no further questions.

EXAMINATION

BY MR. TAMBURO:

Q. Dr. Burks, there was some discussion about work you had performed on behalf of DePuy Mitek; do you recall that?

A. Yes.

Q. Were you compensated by DePuy Mitek for the work you performed?

A. Yes.

MR. TAMBURO: I have no further questions.

MR. FALKE: Okay, thank you for your time.

THE VIDEOGRAPHER: End of deposition, 6:18.

-O-

Deponent's Certificate

I, ROBERT T. BURKS, M.D., deponent herein, do hereby certify and declare the within and foregoing transcription to be my deposition in said action taken on June 7, 2006; that I have read, corrected, and do hereby affix my signature to said deposition.

DATED this _____ day of _______________, 2006.

____
Deponent

)
STATE OF UTAH) ss.
)

SUBSCRIBED AND SWORN to before me this _____ day of ____________________, 2006.

____
Notary Public residing in
____

My Commission Expires:

____

Reporter's Certificate

State of Utah)
County of Salt Lake)

I, Denise Kirk, Certified Shorthand Reporter, Registered Professional Reporter, and Notary Public for the State of Utah, do hereby certify:

THAT the foregoing proceedings were taken before me at the time and place set forth herein; that the witness was duly sworn to tell the truth, the whole truth, and nothing but the truth; and that the proceedings were taken down by me in shorthand and thereafter transcribed into typewriting under my direction and supervision;

THAT the foregoing pages contain a true and correct transcription of my said shorthand notes so taken.

IN WITNESS WHEREOF, I have subscribed my name and affixed my seal this 11th day of June, 2006.

____
DENISE KIRK, CSR/RPR

My commission expires:
August 30, 2006

Johnson & Johnson

Office Of
GENERAL COUNSEL

NEW BRUNSWICK, N.J.

February 3, 1992

SUBJECT: ETH 782 - Entitled "Sterilized Heterogeneous Braids"

B. Schwartz

Barbara, I wanted to let you know that I have been unable to complete this application for filing. It relates to composite braid sutures.

I sent a substantially complete draft, including examples and drawings, to Mark Steckel for review and comment. I then received comments from Chuck Fritz, and I understand that Mark received comments from the remaining coinventors.

I left two voice mail messages for Mark during the first week of January, requesting that he call me to discuss changes to the draft. Dennis Jamiolkowski also requested Mark to contact me. Our requests have gone unanswered.

I'm very sorry that this seems to be a continuing problem. Unfortunately, there is nothing I can do without full cooperation from Mark.

Matt

Matthew S. Goodwin

MSG/sc
cc: C. Fritz

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI095016

EXHIBIT
Steckel 79
2-3-06

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MATTHEW S. GOODWIN

February 10, 1992

Mr. M. Steckel

cc: Mr. M. Banik
Mr. M. Goodwin

Mark, the attached memo has been of great concern to me. I would appreciate your responding to Matt Goodwin's request, and communicating to me your timing with respect to this response.

As far as I am concerned, the work involved is extremely important to the suture business, and given your history with this subject, requires your immediate attention. We are already long past due in filing this patent.

Please contact me as quickly as possible regarding this matter.

Barbara

Barbara Schwartz, Ph.D.

pak

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI095017

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OSTROLENK, FABER, GERB & SOFFEN, LLP

1180 AVENUE OF THE AMERICAS, NEW YORK, NEW YORK 10036-8403
TEL 212 382 0700 FAX 212 382 0888 FAX 212 398 0681 TELEX 236925
email@ostrolenk.com

PARTNERS
SAMUEL H. WEINER
ROBERT C. FABER
EDWARD A. MEILMAN
STANLEY H. LIEBERSTEIN
STEVEN I. WEISBURD
MAX MOSKOWITZ
STEPHEN A. SOFFEN
JAMES A. FINDER
WILLIAM O. GRAY, III
LOUIS C. DUJMICH
CHARLES P. LAPOLLA
DOUGLAS A. MIRO
ALFRED R. FABRICANT

ASSOCIATES
PETER MCGEE*
MARC LIEBERSTEIN
CHARLES C. ACHKAR, Ph.D.
MICHAEL J. SCHEER
ELLEN S. TAO*
PETER S. SLOANE
MARY G. FONTENOT
STEVEN S. RUBIN
WILLIAM A. BONK, III**
MARK D. TORCHÉ
JOEL J. FELBER***
BRENDAN J. KENNEDY***
KOUROSH SALEHI***
RICHARD LACAVA
LAWRENCE C. DRUCKER

OF COUNSEL
MARVIN C. SOFFEN
JEROME M. BERLINER
MARTIN PFEFFER
LEON ZITVER*
LAWRENCE A. HOFFMAN
*DC BAR
**MICHIGAN BAR
***CONNECTICUT BAR

Please reply to:
WASHINGTON OFFICE
1725 K STREET, N. W.
WASHINGTON, D.C. 20006
TEL 202 457 7785
FAX 202 429 8919

November 14, 2000

Mr. Don Grafton
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, FL 34104

Re: OFGS Ref: 3/1493-372
U.S. Patent No. 5,318,575 -- Infringement

Dear Don:

In accordance with your request, we conduct a study to determine if Arthrex's proposed PolyBlend suture (a suture with a reinforced jacket formed of polyester braided with Dyneema®, an ultra high strength polyethylene fiber) infringes U.S. Patent No. 5,318,575 issued to Chesterfield, et al., assigned to U.S. Surgical Corporation (the "U.S. Surgical patent").

Briefly, for the reasons set forth below, it is our opinion that Arthrex's PolyBlend suture, and the method of using the suture for surgical suturing, does not infringe the claims of the U.S. Surgical patent.

The U.S. Surgical Patent:

The U.S. Surgical patent has 12 claims, one of which is independent. Independent claim 1 recites a method of repairing split portions of body tissue. A flexible member (i.e., suture) is looped about the body tissue to hold the split portions together. The suture is made by braiding fibers of an ultra high molecular weight high tenacity material and fibers of another, non-absorbable material.

The prosecution history of the U.S. Surgical patent reveals that the applicants submitted claims drawn to a surgical product comprising an elongated member (suture) formed of fibers of a ultra high molecular weight extended chain high tenacity material braided with fibers of

DEPUY MITEK
EXHIBIT 207
04cv12457

CONFIDENTIAL

ARM 25128

a different material, the "different material" being defined (in some claims) as being non-absorbable. All of these claims were rejected by the Examiner as being unpatentable over U.S. Patent No. 4,819,458 to Kavesh et al. and U.S. Pat. No. 4,792,336 to Hlavacek et al. (copies enclosed). These claims ultimately were canceled by the Applicants. Accordingly, U.S. Surgical relinquished patent coverage of the braided surgical product, and opted to proceed solely with claims directed to the method of using the suture.

As issued, independent method claim 1 recites a method of repairing body tissue by looping the braided surgical product (as described above) "about" split portions of body tissue. Since the braided surgical product was determined to be unpatentable (and the applicant acquiesced in this determination by canceling the product claims), the patentable feature of method claim 1 resides in the step of looping the braided surgical product about the split portions of tissue.

The prosecution history of the U.S. Surgical patent precludes the claimed step of looping the braided surgical product about the split portions of tissue from being construed to include inserting the braided suture product through soft tissue. Significantly, the U.S. Surgical patent discloses the method of looping the suture about tissue (described at col. 4, lines 58 et seq. and shown in Fig. 1) and the method of inserting the surgical product through soft tissue (described at col. 5, lines 41 et seq.) as alternative embodiments. However, the latter embodiment was never claimed. Claims cannot be interpreted in a manner which "recaptures" subject matter which is disclosed in the specification but not claimed. In any event, insertion through soft tissue of a surgical product that contains high strength/modulus polyethylene is not patentable, since it is disclosed in a cited reference, U.S. Patent No. 4,987,665, issued to Dumican et al. (copy enclosed). See col. 6, lines 54-55, col. 13, lines 39-46, and Fig. 3 of Dumican et al. The claims of the U.S. Surgical patent cannot be construed to encompass subject matter in the prior art.

For the foregoing reasons, we conclude that Arthrex's proposed PolyBlend suture and its use in surgical suturing (inserting the suture through soft tissue) does not infringe the claims of the U.S. Surgical patent.

Very truly yours,

OSTROLENK, FABER, GERB & SOFFEN, LLP

Steve

Stephen A. Soffen

SAS/PFM:tj
Enclosure

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ARM 25129

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446 AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

Further, when Arthrex and Pearsalls developed the FiberWire suture, Arthrex created an entirely new category of medical products called high-strength suture. Prior to FiberWire, there was no such product on the market. It is the UHMWPE that makes FiberWire so strong. As I previously mentioned, there is no indication at all within the '446 patent that a high-strength suture was even contemplated by the inventors. To the contrary, the inventors had conceded the fact that there was a tradeoff necessary in having a suture that had better handleability and pliability – that tradeoff was lower strength. That is why the specification repeatedly states that the object of the invention is to achieve better handleability and pliability without appreciably sacrificing physical characteristics, including most specifically, strength. Nowhere is there any description or teaching within the '446 patent that the resulting suture will have strength that is far superior to the prior art sutures identified in the patent. In my opinion, this is another substantial difference.

Putting it in terms of the function/way/result test, as did Dr. Brookstein, it is my opinion that the difference between the function performed by the UHMWPE in FiberWire is very different than that of the first fiber-forming materials of claim 1 of the '446 patent. As I stated above, the function performed by UHMWPE in FiberWire is to impart tremendous strength to the FiberWire suture, whereas the function performed by the first fiber-forming materials is to add lubricity with the recognition that these materials will detract from the strength of the resulting suture. For these same reasons,

Dated: March 24, 2006

Debi Prasad Mukherjee, Sc.D.

DSMDB.2056173.1